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Sexual risk reduction interventions for patients attending sexual health clinics: a mixed-methods feasibility study

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Title: Sexual risk reduction interventions for patients attending sexual health clinics; feasibility to conduct an effectiveness trial

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Abstract (500/500 words)

Background: Sexually transmitted infections (STIs) continue to represent a major public health challenge. There is evidence that behavioural interventions to reduce risky sexual behaviours can reduce STI rates in patients attending sexual health (SH) services. However, it is not known if these interventions are effective when implemented at scale in SH settings in England.

Objectives: The study had two main objectives: 1. develop and pilot a package of evidence-based sexual risk reduction interventions that can be delivered through SH services; 2. assess the feasibility of conducting a randomised controlled trial (RCT) to determine effectiveness against usual care.

Design: The project was a multi-stage mixed methods study, with developmental and pilot RCT phases. Preparatory work included a systematic review; analysis of national surveillance data, and development of a triage algorithm; interviews and surveys with SH staff and patients to identify, select and adapt interventions. A pilot cluster RCT was planned for eight SH clinics; the intervention would be offered in four clinics, with qualitative and process evaluation to assess feasibility and acceptability. Four clinics acted as controls; in all clinics, participants would be consented to a 6-week follow-up STI screen.

Setting: SH clinics in England.

Participants: Young people (aged 16-25 years old) and men who have sex with men.

Intervention: A three-part intervention package: 1. triage tool to score patients as high or low risk of STI infection using routine data; 2. a study-designed webpage with tailored sexual health information for all patients, regardless of risk; 3. a brief one-to-one session based on motivational interviewing for high risk patients.

Main outcome measures: The three outcomes were: acceptability of the intervention to patients and SH providers; feasibility of delivering the interventions within existing resources; and feasibility of obtaining follow-up data on STI diagnoses (primary outcome in a full trial).

Results: We identified 33 relevant trials from the systematic review, including: videos, peer support, digital, and brief one-to-one sessions. Patients and SH providers showed preferences for one-to-one and digital interventions, and providers indicated these intervention types could feasibly be implemented in their settings. There were no appropriate digital interventions that could be adapted in time for the pilot; therefore, we created a placeholder for the purposes of the pilot. The intervention package was piloted in two SH settings, rather than the planned four. Several barriers

were found to intervention implementation, including a lack of trained staff time and clinic space. The intervention package was theoretically acceptable, but we observed poor engagement. We recruited patients from six clinics for the follow-up, rather than eight. The completion rate for follow-up was lower than anticipated (16% versus 46%).

Limitations: Fewer clinics were included in the pilot than planned limiting the ability to make strong conclusions on RCT feasibility.

Conclusion: We were unable to conclude whether a definitive RCT would be feasible due to challenges in implementation of a pilot, but have laid the groundwork for future research in the area. .

Study registration: ISRCTN 16738765.

Funding details: Funded by the NIHR Health Technology Assessment programme (12/191/05).

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List of abbreviations

AttA	Attitudinal Arguments
APP	Application
ASC	Alternative specific constants
BASHH	British Association for Sexual Health and HIV
BIC	Bayesian information criterion
BSA	Behavioural Skills Arguments
BSMS	Brighton and Sussex Medical School
CASH	Contraception and sexual health
CI	Confidence interval
CUST	Condom Use Skills Training
DCE	Discrete Choice Experiment
DH	Department of Health
EPR	Electronic patient record
FPA	Family Planning Association
GMFA	Gay Men Fighting AIDS
GP	General Practitioner
GUM	Genitourinary medicine
GUMCAD	Genitourinary medicine clinic activity dataset
HCP	Healthcare provider
Info	Any kind of Information
IST	Interpersonal Skills Training
LGV	Lymphogranuloma venereum
MI	Motivational Interviewing
MRC	Medical research council
MSM	Men who have sex with men
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NormA	Normative Arguments
NPV	Negative predictive value
OR	Odds ratio
PEP	Post-exposure prophylaxis

PHE	Public Health England
PPI	Patient Public Involvement
PPV	Positive predictive value
PREP	Pre-exposure prophylaxis
RCT	Randomized Controlled Trial
RSB	Risky sexual behaviour
RR	Relative risk
SH	Sexual health
SMT	Self-Management Training
STIs	Sexually transmitted infections
THT	Terrence Higgins Trust
TIA	Threat-inducing Arguments
UAI	Unprotected anal intercourse
UCL	University College London
UK	United Kingdom
USA	United States of America
WP	Work package
YP	Young person, aged 16-25 years old

Plain English summary (298/300 words)

Reducing sexually transmitted infections (STIs) is a public health priority. Those most likely to be diagnosed with an STI are men who have sex with men and young people (16-25 years old). Interventions aimed at changing sexual behaviours (e.g. increasing condom use), can reduce the chance of getting new STIs in patients attending sexual health clinics. However, it is not clear if these interventions will work in English sexual health clinics, or if they could be implemented within existing resources. We aimed to find out if effective interventions could be adapted to an English setting and tested in a randomised trial.

We searched the scientific literature for potential interventions, and found 33 trials. Effective methods included: videos, digital web-based interventions, self-testing kits, and talking sessions (e.g. counselling). We asked patients and providers which interventions were acceptable and found preferences for digital and 1:1 talking interventions. Providers suggested these were feasible to deliver. We used data routinely collected from patients (e.g. number of partners), to select patients at higher risk of having an STI, and developed a computerised risk score calculation, and direct the highest risk group to a 1:1 counselling intervention. There were no appropriate digital interventions available; we therefore created a stand-in webpage to signpost users to appropriate sexual health resources. This was offered to all patients.

The intervention package was piloted in two sexual health settings, rather than the planned four due to lack of clinic staff time and space. We planned to follow-up a sub-set of patients from all 8 clinics 6-weeks after their visit, to collect information on STI diagnoses. Patients were recruited from six clinics, but only 16% completed the survey and returned a sample.

We were unable to definitively conclude whether a randomised trial is feasible due to challenges in implementation and recruitment.

Scientific summary (1,838/2,400 words)

Background:

Sexually transmitted infections (STIs) continue to represent a major public health challenge in the UK, with 417,584 diagnoses in 2016. Although there have been reductions in the number of cases of gonorrhoea and genital warts, there was a 12% increase in syphilis diagnoses, and chlamydia incidence has remained stable. Despite having a national network of open-access clinics for the treatment of STIs, and improved diagnostics, infection rates remain high. STIs particularly affect sub-groups of the population, with young people (<25 years) and men who have sex with men (MSM) having the highest rates of infection. A variety of factors contribute to the risk of STIs: lack of knowledge about STIs; low self-efficacy; poor condom use; peer norms; and a lack of sexual negotiation skills. This has led to the Department of Health's Sexual Health Framework prioritising prevention and support for behaviour change, alongside access to sexual and reproductive health services, particularly for those most vulnerable to poor sexual health.

Multiple behavioural interventions have been trialled, and in most cases shown to have a modest but consistently positive effect, but they have not been implemented systematically in a way that could have a population level impact in the UK. There is a lack of evidence about how they can be implemented, in which context, by whom, and for whom. A clearer understanding of the factors that influence implementation in particular settings is needed. As funding for healthcare is under pressure, providing substantial additional resources across a large number of services is unrealistic, and therefore implementation of new interventions needs to focus on identifying brief, pragmatic, labour non-intensive interventions that can be tailored to the level of risk of the individual attending any of a range of different SH services. Implementation should be achievable with reallocation of existing resources, not substantial new investment.

Objectives:

The overall aim of the project, developed in response to a commissioned call, was to determine the feasibility of a randomised controlled trial (RCT) of an individualised package of sexual risk reduction interventions, to be offered within routine clinical care pathways in SH clinics. This aim was addressed through ten objectives:

1. To review existing evidence relevant to the UK on the nature and efficacy of brief and self-delivered sexual risk reduction interventions
2. To identify a suite of interventions of known effectiveness that can be delivered and combined to meet individual users' needs
3. To develop a sexual risk assessment/triage tool to identify service users' level of sexual risk and thus individualise packages of behavioural interventions to the user's needs
4. To describe current practice in UK SH clinics with respect to delivery of sexual risk reduction interventions and identify best practice
5. To explore opportunities and challenges to the delivery of candidate risk reduction interventions in SH clinics
6. Using stakeholder input, to select, adapt and develop a manual of the evidence-based suite of interventions that can be combined and delivered to meet individuals' needs
7. To determine the acceptability, feasibility and deliverability of the individualised intervention packages in different SH clinical settings
8. To assess the feasibility of testing the effectiveness of this individualised package of behavioural interventions in a randomised controlled trial (RCT) against usual care
9. To estimate the cost and resource implications of implementing the individualised intervention packages in different SH settings
10. To refine a manual of the intervention packages and to outline a feasible trial design (if feasibility is supported)

Methods:

The project was a multi-stage mixed methods study, which included developmental work and a pilot cluster randomised control trial, and comprised six packages of work, using the methodological approach of intervention mapping.

The developmental work included three main strands of work to inform the intervention package design: a systematic review of sexual risk reduction behavioural interventions focussing on UK relevant evidence; development of a sexual risk triage tool to identify individuals at increased risk of STI diagnosis; a mixed methods study to describe sexual risk reduction practices and preferences in sexual health clinics and to identify opportunities for intervention. Using the evidence generated

from these activities, we selected and adapted evidence-based intervention components to develop and manualise a 1:1 intervention. We sought feedback from patients and healthcare providers (HCPs) on the design and content of the intervention.

We conducted a pilot cluster randomised trial to investigate the feasibility of implementing the intervention package, its acceptability, and the feasibility of obtaining outcome data necessary for a full RCT. The pilot was designed to include four intervention and four control clinics, including level-2 and level-3 services. A sub-set of patients were recruited from intervention and control clinics, to be followed up 6-weeks later for a web-survey and STI screen. The STI screen was offered as either a postal self-sample kit, sent to patient's home, or patients returned to the clinic for a screen. The screen included chlamydia and gonorrhoea tests. The web-survey collected information about their recent clinic visit, including any interventions received.

In the intervention clinics, process data was collected from the electronic patient record system, or study data collection tools to monitor engagement with the intervention. Interviews and focus group discussions were conducted with patients and HCPs to gain feedback on the acceptability and feasibility of the intervention delivery.

Results:

Developmental work: we identified 33 RCTs in a systematic review, of which 24 provided evidence of some significant impact on sexual behaviours, reflected in increased testing for STIs, or reduced STI rates. Interventions included videos, digital online, peer-group delivered, talking interventions, such as counselling, or provision of self-sampling kits for STI testing. Feedback from both patients and providers indicated that talking interventions, such as brief motivational interviewing sessions, and digital interventions were considered acceptable to service users and desirable by HCPs. HCPs also indicated that these intervention approaches could feasibly be delivered within their clinical settings.

We developed an intervention package, consisting of three components: 1. A triage tool to score patients as high or low risk of STI infection using routine data; 2. A digital intervention (webpage) for all patients, regardless of risk (low-intensity intervention); 3. A brief one-to-one consultation based on motivational interviewing for high risk patients (high-intensity). There were no appropriate online interventions that were available, or that could be adapted for the pilot; therefore, we created a placeholder for the purposes of the pilot.

Pilot intervention: We enrolled 8 pilot trial sites in 4 categories (level 2; small, medium and large level 3 GUM), and allocated these as 4 intervention and 4 control sites. Neither level-2 service (one intervention, one control) were able to implement the protocol. Among the remaining three intervention sites, the intervention package was implemented fully in one, partially in one and was not able to be piloted in the third. Principal barriers to site participation included: re-commissioning of services during the period of the pilot; lack of staff capacity or space; other changes such as implementation of a new EPR system, or re-location of the clinic. A search for replacement clinics for those unable to deliver was unsuccessful.

The triage process was completed by 612 eligible patients in the intervention sites. The triage threshold was set to select 5% of young people and 15% of MSM as being at high-risk, based on the model development process. However when implemented, considerably more than this (19% young people, 29% MSM) were selected. Of those triaged as high risk, 18% attended the one-to-one session, and 0.4% of clinic attendees (both high and low-risk were eligible) were tracked as having visited the webpage.

Patient and provider participants in the qualitative interviews and focus group discussions gave positive feedback about the one-to-one sessions, with health advisors feeling it was similar to, and reinforced their current roles, and patients who attended stating they found it acceptable. There were mixed views of the triage process, particularly from HCPs; there were difficulties in implementing the triage process within the clinic EPR systems in a reasonable timescale, so that alternative processes had to be used (self-completion tablet-computer questionnaires on arrival in the clinic). Participants felt that the principle of a web-based intervention was good, but neither HCPs nor patients had actively engaged with this part of the intervention package, which was limited by our inability to offer a fully functioning intervention.

Pilot follow-up: We recruited 406 patients to test whether it was possible to collect follow-up data at 6 weeks. This comprised a web-survey and STI screen (by self-sampling, and return by post). Of those enrolled, 273 (67%) were young people and 133 (33%) were MSM. 228 (56%) participants did not participate in either the web-survey or return a self-sample kit and 64 (16%) completed both. Young people were less likely to complete the web-survey (OR: 0.39, 95% CI: 0.25, 0.61), or complete an STI screen (OR: 0.45, 95% CI: 0.29, 0.72) than MSM. Amongst young people, women were more likely to participate than men, and there were significant differences in follow-up rates by clinic, even when the age, gender and ethnicity of the participant were taken into account. Among MSM, no demographic factors were significantly associated with response, although there were trends towards older and white MSM responding.

Conclusions:

There are existing evidence-based interventions that could benefit patients attending UK sexual health services. We adapted and manualised a brief one-to-one intervention that was acceptable to staff and patients, although we had very limited opportunity to pilot it in clinics. However digital format interventions, while acceptable and more easily deliverable at scale, were not available to pilot. They required more adaptation than was possible within the remit of this project, and a commitment to longer term maintenance and updates. A mechanism to triage patients as part of routine care was developed, but before large scale testing it would require more engagement by software suppliers so that it could be incorporated into EPR systems. During piloting, we found some evidence to support the acceptability of the combined intervention package, but encountered multiple challenges in both the feasibility of implementation and conduct of a trial. Follow-up rates for the outcome measure were lower than anticipated. Therefore, we conclude that undertaking a cluster RCT of the proposed intervention package would be very difficult in the environment of current sexual health service provision in England. In addition to the challenge of limited resources and service re-organisation, there is a change in the model of care being commissioned, with a shift away from face-to-face consultation, to self-testing and online patient pathways. While there is agreement that there is a need for behavioural interventions, including one-to-one for the highest risk groups, the heterogeneity of services means that implementation of a large-scale national trial would be challenging. Digital interventions could be implemented in conjunction with new care pathways for STI testing but these have not been widely commissioned. Further developmental work is required to see how behavioural interventions can be incorporated into the new models of service delivery. Alternative evaluation designs are likely to be required to provide evidence of efficacy and cost-effectiveness at that point.

Study registration:

ISRCTN 16738765.

Chapter 1: Background, aim and overview

1.1 Background

Sexually Transmitted Infections

In 2012, there were 448,422 new diagnoses of sexually transmitted infections (STIs) made in England.[1] This declined to 417,584 diagnoses in 2016, with reductions driven mostly by gonorrhoea and genital warts. However a concurrent 12% increase in syphilis diagnoses was seen, and chlamydia incidence has remained stable.[2] There has also been a considerable decline in the number of new HIV diagnoses between 2015 and 2016, with a 23% reduction in men who have sex with men (MSM) largely attributed to increased HIV testing and pre-exposure prophylaxis (PrEP).[3, 4]

Despite improved diagnostics, widespread service provision for the treatment of curable STIs in England, and greater emphasis on partner notification, infection rates remain high. STI rates are particularly high in sub-groups of the population, with young adults (<25 years) and MSM having the highest rates of infection.[1, 2] Many STIs in young people will go undiagnosed and for young women in particular, this may have consequences for their future fertility, and consequent costs for the health service. Individuals may be at risk for a variety of reasons such as lack of knowledge about STIs, low self-efficacy (lacking belief that one can successfully meet a goal or perform a particular task such as negotiating the using of condoms), poor condom use and/or sexual negotiation skills. Risk-taking may also be influenced by peer-group norms. Some groups of young people, often characterized by factors associated with the broader determinants of social and health inequalities e.g. education and literacy, are disproportionately affected by STIs.[5]

This has led to the development of a Sexual Health Framework by the Department of Health, which prioritises prevention and support for behaviour change, alongside access to sexual and reproductive health services, particularly for those most vulnerable to poor sexual health.[6] This is especially crucial in the context of increasing antibiotic resistance, for example in gonorrhoea,[2] where prevention of infection is as important as effective treatment, if we are to bring transmission rates down.

Sexual Health Services

Sexual health (SH) services are provided through a range of clinics in England, including GP practices, genitourinary medicine (GUM) and contraception clinics, young people's services (including third sector providers such as Brook) and pharmacies. The types of care that these different providers' can offer ranges. Level-3 services (e.g. GUM clinics) provide the full range of STI testing, treatment and

management for all patient groups, usually with contraceptive services, as integrated sexual health services. Level-2 services (e.g. some community sexual health services, Brook or enhanced GP services) provide more limited STI testing and management of uncomplicated or asymptomatic infections. Level-1 services offer limited STI screening for asymptomatic patients only.[7]

Since 2013, the commissioning of NHS services for sexual health has changed, become more complex, and fragmented. Most services are now commissioned by local authorities, as part of their remit to provide public health services. NHS England remains responsible for HIV treatment and care, but also commissions some components of sexual health, such as national screening programmes. Clinical commissioning groups (CCGs) also have a role, through their responsibility for commissioning primary care services.[8-10] Clinics that provide sexual and reproductive health services offer an opportunity to engage those at risk in sexual risk reduction interventions.[11, 12] However, introducing complex triage and sexual risk reduction interventions into busy clinical settings on a large scale, essential if there is to be a population level impact, is challenging and will have resource implications. It is imperative to show that a complex intervention is effective and deliverable, as well as cost effective, in a sufficient proportion of the diverse range of services provided in England.

Risk groups and behaviours

Young people and MSM are at higher risk of STIs. MSM specifically are at risk of HIV infection, with more than one third of newly diagnosed HIV cases in Western Europe being amongst MSM.[13] In addition to age and sexual orientation, several demographic, geographical and behavioural characteristics have been identified which are associated with an increased risk of STIs. This potentially allows for targeted provision of prevention services to sub-groups at highest risk of STI acquisition.

Amongst young people, factors associated with an increased risk of a STI diagnosis include: multiple partners, previous STI diagnosis and reported lack of condom use. In England specifically, the relative level of deprivation and the geographical region where someone lives are also associated with STI risk.[2, 14, 15] Similar patterns are seen amongst MSM, with associations with multiple partners and geographical variations observed.[16, 17] There are also differences in STI diagnoses according to ethnicity, with gonorrhoea rates being considerably higher amongst black ethnic minorities.[18] In addition, the use of drugs during sex ('chemsex'), is a pronounced risk factor amongst MSM groups, although also seen as a risk in heterosexuals.[16, 19, 20] Information about these factors are often routinely collected within SH services as part of taking a clinical history, and could therefore be used as part of triage processes.

Risk reduction interventions

Behaviour change interventions seek to promote changes in behaviour patterns associated with STI acquisition. The white paper 'Healthy Lives, Healthy People' emphasises a commitment to behaviour change approaches as a solution to reducing preventable illness and death.[21] Research has shown that behaviour change interventions can help people adopt health-promoting behaviour patterns, including safer sex practices.[22, 23] However, intervention effectiveness varies in relation to intervention type and target audience.[24, 25] Attendance at a SH clinic provides an opportunity for intervention delivery at a potentially 'teachable moment', when people are primed to think about their sexual behaviour and the consequences for their health.[26]

Sexual risk reduction interventions are complex interventions, which at the same time need to be integrated into routine service provision alongside STI testing and treatment, repeat testing and partner notification. These interventions can take a number of forms, and have different objectives, such as increasing knowledge of STI's; changing cognitive antecedents, such as attitudes and/or beliefs (including normative beliefs); or increasing self-efficacy.[27] The mode of delivery can vary widely. The US Centers for Disease Control and Prevention Community Guide concluded that community-based individual, group, and community-level interventions can be effective in reducing the risk for STIs in MSM.[27] Digital approaches, such as 'apps' or online interactive interventions have also be shown to be effective and offer novel delivery which can be done outside of the clinic environment.[28] Other intervention formats, such as waiting-room videos can be provided to all clinic attendees, although they may need adapting to different clinic settings; they have been shown to reduce incident STIs.[29] However there is also evidence that tailoring interventions to individuals' preferences and needs leads to greater uptake, and makes them more likely to be effective.[30]

As clinic resources are limited, the use of triage or risk assessment can ensure that more resource-intensive interventions are targeted at those who need them most, or for whom the intervention has been designed, and is more likely to be effective. As electronic patient record (EPR) systems become more widely used within clinical settings, using the coded data collected as part of routine care to inform a triage algorithm, could provide a mechanism to target different risk groups with appropriately tailored risk-reduction support.

Evidence-gap

Currently, multiple interventions have been trialled but there is a lack of clarity about which intervention would best be implemented in which context, by whom, and for whom. Therefore, a clear understanding of the factors that influence implementation in particular contexts is needed. In addition, such interventions, while tested individually and in most cases showing a modest but

consistent positive effect, have not been implemented systematically in a way that could have a population level impact in the UK. An additional challenge is that any implementation can only be achieved if it can be delivered at minimal overall cost. As funding for healthcare services, particularly those commissioned by local authorities is under pressure, any demand for additional resources across a large number of services is unrealistic. In this context, research is required to identify brief, pragmatic, labour non-intensive interventions that can be tailored to the level of risk of the individual attending any of a range of different SH services. The characteristics of those in the higher risk groups will differ by clinic setting, gender, sexual orientation and other factors which will need to be incorporated into the intervention model. The HTA call which led to the work described in this report was intended the address a first, important step by determining whether it would be feasible to conduct a definitive trial of effectiveness of brief behavioural interventions in sexual health services, incorporating the development of triage process to ensure that the interventions were most efficiently delivered to those most likely to benefit, and whether such a strategy meets is acceptable on cost-effectiveness criteria.

1.2 Aim

The overall aim of the project was to determine the feasibility of a randomised controlled trial (RCT) of an individualised package of sexual risk reduction interventions offered within routine clinical care pathways in SH clinics. This addresses two key aims:

1. To develop and pilot a package of evidence-based sexual risk reduction interventions for those at most risk, that can be implemented in SH services. The suite of interventions will be matched to service users' needs and developed alongside a triage method for identifying target groups.
2. To assess the feasibility of testing the effectiveness of this individualised package of behavioural interventions in an RCT against usual care.

1.3 Objectives

The aims were addressed through ten specific objectives:

1. To review existing evidence relevant to the UK on the nature and efficacy of brief and self-delivered sexual risk reduction interventions
2. To identify a suite of interventions of known effectiveness that can be delivered and combined to meet individual users' needs
3. To develop a sexual risk assessment/triage tool to identify service users' level of sexual risk and thus individualise packages of behavioural interventions to the user's needs
4. To describe current practice in UK SH clinics with respect to delivery of sexual risk reduction interventions and identify best practice
5. To explore opportunities and challenges to the delivery of candidate risk reduction interventions in SH clinics
6. Using stakeholder input, to select, adapt and develop a manual of the evidence-based suite of interventions that can be combined and delivered to meet individuals' needs
7. To determine the acceptability, feasibility and deliverability of the individualised intervention packages in different SH clinical settings
8. To assess the feasibility of testing the effectiveness of this individualised package of behavioural interventions in a randomised controlled trial (RCT) against usual care
9. To estimate the cost and resource implications of implementing the individualised intervention packages in different SH settings
10. To refine a manual of the intervention packages and to outline a feasible trial design (if feasibility is supported)

1.4 Project Overview

The project was a multi-stage mixed method study design that incorporated: a systematic review; secondary analysis of national surveillance data; interviews and surveys with clinic staff; semi-structured interviews, a discrete choice experiment and focus groups with clinic attendees; monitoring of intervention offering, uptake, and completion, and follow-up questionnaires; and capturing the clinical resources used. In order to achieve this, the study was organised into 6 overlapping work packages (WP), summarised below (**Figure 1**):

Work Package 1: A systematic review of sexual risk reduction behavioural interventions focussing on UK relevant evidence (Objective 1 & 2).

Work Package 2: Development of a sexual risk assessment/triage tool to identify individuals at increased risk in SH settings (Objective 3).

Work Package 3: A mixed methods study to describe sexual risk reduction practices and preferences in SH clinics in the UK and to identify opportunities for intervention (Objectives 4 & 5).

Work Package 4: The selection and adaptation of a suite of evidence based interventions suitable for delivery in SH settings and acceptable to patients and staff (Objective 6).

Work Package 5: A pilot study of the feasibility of implementing interventions, to assess their acceptability, practicality, and cost of implementation; to comment on the feasibility of a future randomised control trial (Objectives 7-9).

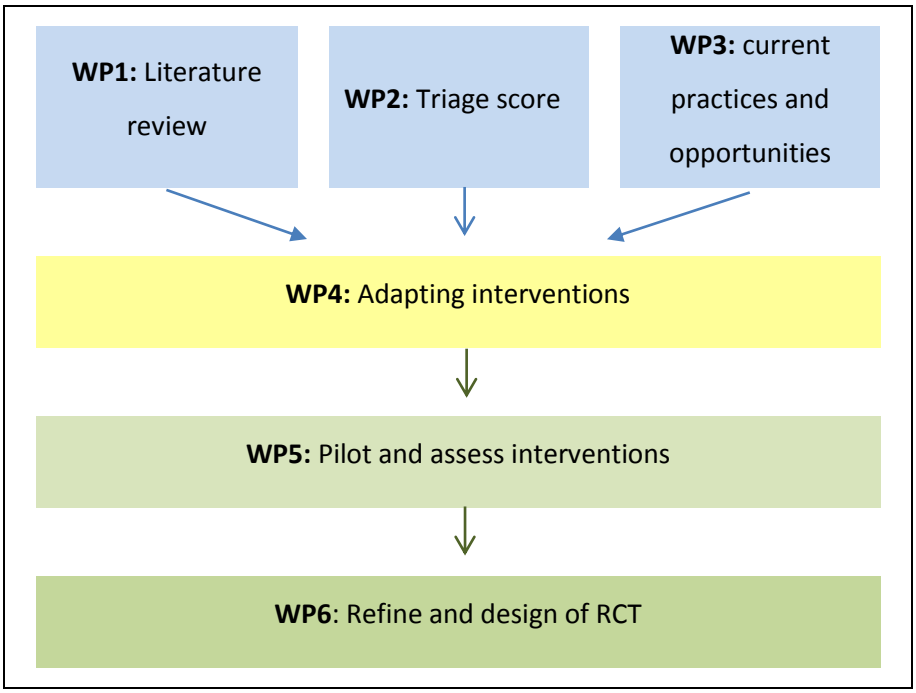
Work Package 6: The refinement of the triage tool and manuals of the interventions to ensure that the triage tool can be incorporated into routine care (or derived from routinely collected data) and to ensure the fidelity of the interventions; an outline of the trial design for a full evaluation (Objective 10).

The project focussed on understanding factors that influence implementation of interventions in complex SH clinic settings, from both patient and provider perspectives. We used co-creation approaches to intervention identification and adaptation with health advisors, clinicians and service users as an essential part of ensuring that the intervention would be acceptable and deliverable. We followed the Medical Research Council (MRC) revised guidance on developing and evaluating complex interventions,[31, 32] taking the results of the systematic review and selecting and developing the most promising package of interventions to reduce sexual risk. The National Institute for Health and Care Excellence (NICE) and the Department of Health, recommend user input when designing services as it leads to services that are more responsive to the needs of users as services are less likely to be designed inappropriately and more likely to be used.

The methodological steps to delivering the objectives set out above were informed by the Intervention Mapping (IM) approach to intervention design.[33] The IM approach is iterative and can be described as 6 steps (see **Box 1**). As described, the views of stakeholders, including service users and staff who deliver interventions, are captured and are vital to the successful design and implementation of interventions that are acceptable, practically feasible and sustainable over time.[34] Co-creation of interventions with stakeholders is integral to the IM approach.[33] Although in part already defined by the project brief, the project included consideration of the needs of the population, and identified specified behaviour change outcomes corresponding to those needs.

Regulatory processes underpinning specified behaviour changes were identified from relevant research and matching change techniques selected.

Figure 1: Work Package Overview



In the case of the interventions, it was anticipated that as these were to be selected from those for which efficacy evidence already existed, that we would be able to select practical intervention-components designed to change defined behaviour regulation processes that work in-situ.

This IM process facilitates identification of primary and secondary outcome measures, specified as needs and target behaviour changes, thus anticipating the evaluation design. Prototype interventions should be tested and adapted to ensure fidelity of delivery in context, prior to finalising an intervention manual.

The IM process combines an ecological approach with participation of all stakeholders, a focus on specification of the underlying mechanism (in a clear logic model), and a research-based approach to ensuring fidelity of implementation. A key part of this process is to identify change techniques (e.g. Abraham & Michie, 2008 (124); Abraham 2011 (125); Michie & Johnston, 2012 (126)), modes of delivery and delivery competencies that maximise intervention effectiveness in real-world contexts (110). All of this underpinned the approach taken to deliver the project.

Box 1: Intervention Mapping: six iterative steps applied to the Santé Project

1. Needs assessment (partially pre-determined by commissioned brief, and part by WP1 and WP3)
2. Mapping of intervention objectives (i.e. main outcomes) onto psychological, behavioural and environmental determinants or change processes (WP4)
3. Selecting techniques and strategies to modify the determinants of behaviour based on an understanding of change processes (WP4)
4. Selection and construction of intervention components and materials (WP4)
5. Planning for intervention adoption, implementation and sustainability (WP5)
6. Planning evaluation including process and outcome evaluation methods and instruments (partially by WP5)

1.4.1 Project Management

Structured oversight of the project was conducted by a Project Steering Committee (PSC), with an independent chair, and was convened according to guidelines from the NIHR HTA Programme. This committee also served the function of the Data Monitoring Committee.

The Project Management Group (PMG), chaired by the CI oversaw the work of all work packages. It played the role of agreeing the details of project set-up, design, initiation and supervision of the study. Each work package had a WP working group responsible for day to day management of the work, and this reported to the PMG monthly.

1.4.2 Patient Public Involvement

We embedded patient and public involvement (PPI) into the research programme at key points, including at the proposal development stage. It was essential that the developed intervention packages were endorsed by service users, therefore PPI and service user input throughout the proposal was sought for the translation of the research outcomes into improvements in current service provision. We set up a PPI group specifically for this project and liaised with them throughout the project. The PPI group (including our target groups of young people and MSM) helped in writing and approved the patient information sheets for this study.

1.4.3 Ethics

Ethical approval for the study was granted by Westminster National Research Ethics Committee (ref: 15/LO/0690) for work conducted in work packages 3 and 4, and the Chelsea National Research Ethics Committee (ref: 16/LO/0673) for work conducted in work package 5. The use of data in WP2 was approved by Public Health England's Associate Caldecott Guardian. The anonymised data was collected as part of a pilot of enhanced routine STI surveillance, and the use of it was not considered to require ethical review. All service user participants provided written informed consent for interviews, focus group discussions and surveys. Healthcare providers provided written informed consent for focus group discussions, verbal consent for interviews and implied consent for web-surveys. Process data from clinics was anonymised, and posters informing service users that the clinic was currently part of a study were displayed informing them that they could opt-out of their process data being used in analysis.

Chapter 2: Work Package 1 – Systematic Literature Review

2.1 Background

A 2010 meta-analysis of sexual risk reduction interventions suggested that behavioural interventions are effective, with moderate effect sizes, and should be implemented widely to reduce the population burden of STIs including HIV.[30] However, this review focussed solely on USA-based intervention studies within STI clinics. An earlier UK review of behavioural interventions in GUM clinics, included 14 trials, but 12 were conducted in the USA.[35]

Potential interventions could include those delivered in the clinic setting, such as brief 1:1 motivational interviews, or beyond the clinic visit, such as interactive digital interventions. A recent review of interactive digital interventions has confirmed that they can be effective in improving knowledge about sexual health and suggest that they influence sexual behaviour positively; however evidence of an effect on STI rates was lacking.[36] Other systematic reviews of interventions have been limited to particular groups, such as: adolescents,[37-41] HIV-positive individuals,[42] older adults,[43] MSM[44] or have focussed only on condom promotion,[45] or HIV risk.[46]

There was a need to update these systematic reviews to include brief interventions that could be delivered in the wider range of sexual health services available in the UK (e.g. GUM, CASH and Brook services), focussing on the highest risk groups of MSM and YP. This chapter has been published previously. [47]

2.2 Aim

The aim of this review was to identify evidence-based waiting-room-delivered, self-delivered and brief-healthcare provider-delivered interventions that evaluated effectiveness against reducing risky sexual behaviour or incidence of STIs in both young people and MSM.

2.3 Methods

A review protocol was developed and set out the methods used in the review (PROSPERO registration number: CRD42014014375). The review was conducted in 2015.

2.3.1 Search strategy

The search strategy was developed in MEDLINE (OVID) and adapted for use in other databases. The search used a RCT filter to identify methodologically relevant studies. Search terms were identified by consulting literature, and an iterative search process was used to ensure an appropriate balance of sensitivity and specificity. MeSH terms used in the original MEDLINE search were translated for use in other databases as necessary.

The following databases were searched: MEDLINE (OVID); PsycINFO (OVID); EMBASE (OVID); CINAHL (EBSCO); CENTRAL; DARE (via Cochrane); HTA (via Cochrane). All searches were conducted in October 2014. Further searching was carried out by hand of references of retrieved studies and relevant systematic reviews. The database search results were exported and managed using to Endnote (X5) and de-duplicated using the software and manual checking. A full search strategy is presented in **Appendix 1**.

2.3.2 Study selection

We considered only individual and cluster RCTs. Relevant studies were identified in two stages using predefined eligibility criteria. Titles and abstracts were examined independently by two researchers and screened for possible inclusion. Disagreements were resolved by discussion. Full texts of the identified studies were obtained. Two researchers examined these independently for inclusion or exclusion. Gwet's AC1 statistic was calculated to assess inter-rater reliability [48] and disagreements were resolved by discussion. A third reviewer was available if necessary.

2.3.3 Inclusion criteria

Population: Young people aged 16-25 years or MSM groups

Study design: RCTs of brief interventions for reducing sexual risk that could be implemented in sexual health clinics in the UK were considered. Within this definition, interventions were divided into those that involved one 30-minute (or less) session, and those that involved between two and six 30-minute sessions. The analysis was restricted to RCTs to increase the likelihood that evidence of effects would be robust.

Intervention: Interventions in the following settings were included: social networking sites; primary care; emergency care settings; community treatment settings e.g. GUMs and sexual health clinics;

educational settings (including schools and colleges). Waiting room tasks, self-delivered, clinician delivered and digital interventions were included.

Outcome: biological (e.g. STI incidence), sexual behaviours (e.g. condom use or number of sexual partners), testing (e.g. home-based, appointment booking and clinic visits). Outcomes were measured at a minimum of 60 days follow-up. [Note: we included studies that did not show statistically significant effects on primary or secondary outcomes].

Setting: The UK and other high-income settings.

2.3.4 Exclusion criteria

Population: Studies focused exclusively on victims of sexual or domestic abuse or violence, those in prison or psychiatric facilities or nursing homes or individuals / communities with no fixed address.

Study design: studies without a randomised control group; animal models; narrative reviews, editorials, opinions; non-English language papers; and, reports published as meeting abstracts only, or where insufficient methodological details are reported to allow critical appraisal of study quality. Systematic literature reviews were not included in the review, but their reference lists were searched for relevant RCTs. Studies published prior to 2000 were excluded.

Intervention: All non-tailored interventions (e.g. social marketing campaigns providing free access to condoms); interventions for adherence to medical treatment (e.g. adherence to ARVs); Interventions for couples and family/parent-centred interventions.

Outcome: psychological changes only evaluated, such as attitude change, or a follow-up of less than 60 days.

Setting: Low or middle-income settings.

2.3.5 Critical appraisal

The methodological quality of each paper was assessed using the Cochrane 'risk of bias' tool [49]. The tool includes six key criteria against which potential risk of bias is judged: adequacy of allocation sequence generation; adequacy of allocation concealment; blinding of participants, personnel or outcome assessors; completeness of outcome data; selectivity of outcome reporting, and other

biases. Quality was assessed by one reviewer, and checked by a second. Any discrepancies were discussed and resolved and reviewed by a third reviewer.

2.3.6 Data extraction

Data on the study design, setting, population, intervention, outcomes and results were collected using a standardised data extraction form. Data were extracted by one reviewer and 50% checked for accuracy by the second reviewer.

2.3.7 Analysis

Findings of each RCT were summarised alongside a narrative synthesis. The summaries qualitatively examined the range of results and potential associations with effect size. Additional potential moderators or mediators that we examined included characteristics of the interventions (e.g. degree of tailoring), intervention components (e.g. condom use skills training), and population (sex, sexual orientation and co-existing conditions). Intervention components were categorised into ten categories based on Albarracin et al.[25] – summarised in **Box 2**. The ten intervention component categories were: normative arguments (NormA), attitudinal arguments (AttA), behavioural skills arguments (BSA), information (info), threat-inducing arguments (TIA), condom use skills training (CUST), interpersonal skills training (IST), self-management skills training (SMT), condom provision (CP) and HIV/STI counselling and testing (HIV/STI testing). Components were independently coded for each intervention description by one reviewer and 50% were independently coded by a second reviewer. Gwet's AC1 statistic was calculated to assess inter-rater reliability.[48]

2.4 Results

The search yielded 17,916 unique publications (**Figure 2**). Titles and abstracts of all publications were screened by two independent reviewers. Inter-reviewer agreement, assessed with Gwet's AC1 statistic[48] was nearly perfect (99% agreement; AC1 = 0.99) for study screening and selection. 84 articles were identified for full text screening and 33 studies were included in the review. Data were extracted and rated on all the intervention strategies by one reviewer and a second reviewer extracted 50% of the data independently; inter-rater reliability was excellent (80.6% percent agreement; AC1=0.86).

2.4.1 Study Descriptions

Of the 33 studies included, 23 were focused on young people and 10 on MSM groups. The majority of studies were based in the USA, including all 10 of the MSM and 16 of the YP studies; other YP studies were from the UK (n=3), Australia (n=2) and one each from the Netherlands and Denmark. A summary of the studies is presented in **Table 1**.

Many interventions were culturally tailored to a target group, usually based on age, gender, sexual orientation and ethnicity and the types of interventions evaluated were very heterogeneous. The majority of interventions were aimed at reducing high-risk sexual behaviours (e.g. condomless sex or multiple partners) and maximising protective behaviours. Many interventions provided basic information about STIs and commonly included risk assessment, hands-on skills training in condom use, problem solving, decision making, goal setting, and communication around safe sex. Five studies also included additional testing components.[50-54] Intervention delivery used print, mail, computer, or video-based formats and included face-to-face counselling with varying levels of intensity, from 1 short session up to 2 hours contact time.

The most commonly reported outcome was condom use or unprotected sex, alongside other self-reported behavioural outcomes (16/23 YP and 9/10 MSM studies). Twelve studies reported on at least one STI outcome (9/23 YP and 3/10 MSM studies), with chlamydia and gonorrhoea being the most frequent.[52-62] STIs diagnosed at recruitment, or baseline, were treated therefore bacterial infections at follow-up were considered new infections. For studies that included viral infection outcomes, only infections after baseline assessment were counted in the results. Most of the studies collected their own samples at follow-up, and many supplemented this with medical record reviews.

Overall 24 of the 33 RCTs reported some effectiveness against either the primary or secondary outcomes. We retained non-effective studies in the review to allow a comparison of those strategies which did not work. A reduction in STI incidence was reported in half of the young people studies which evaluated this (4/8 studies), and 8 of the 16 to report on behavioural outcomes found a beneficial effect. Of the three trials which reported STI outcomes in MSM, none showed any effect,[52, 61, 62] but the majority of those reporting on behavioural outcomes reported beneficial results for at least one measure.

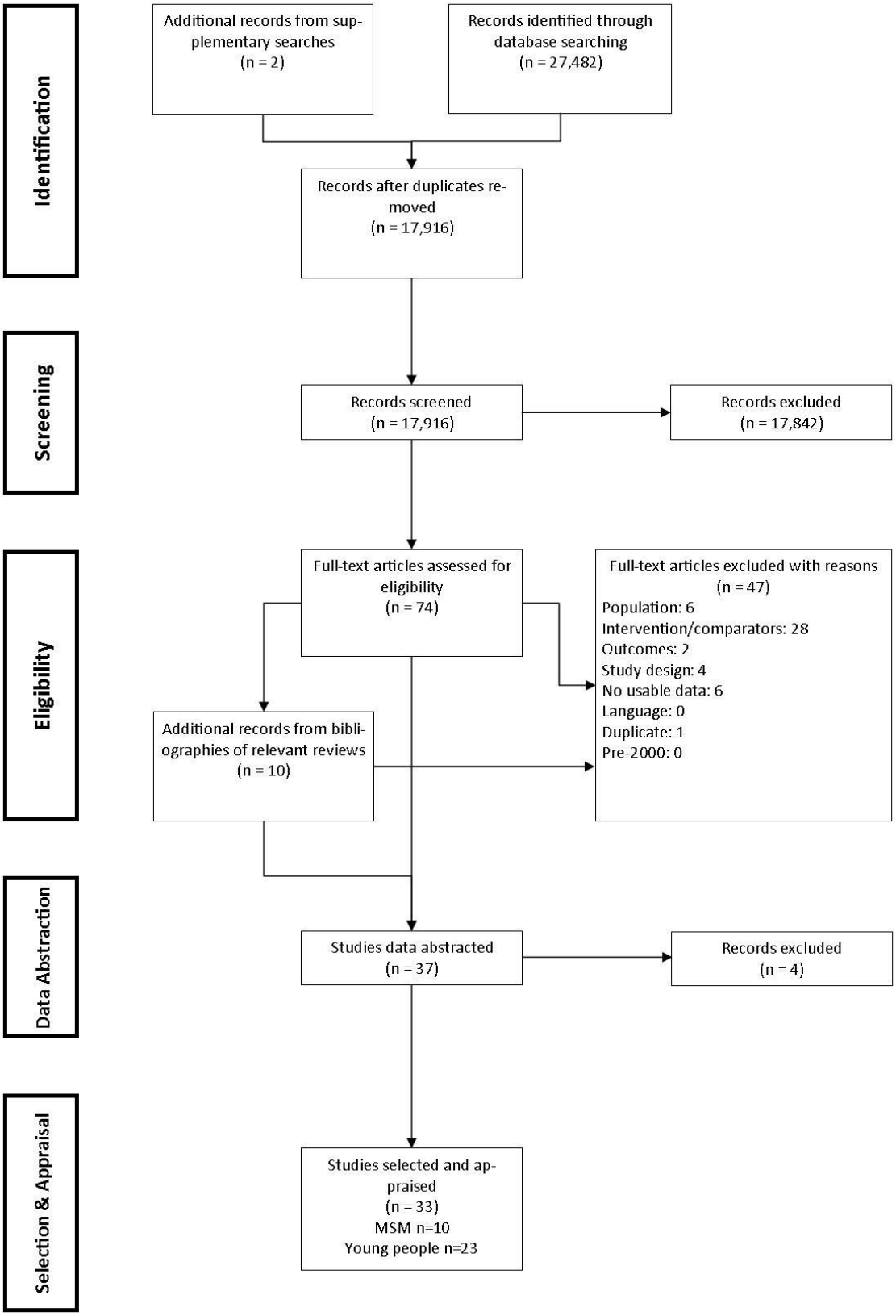

Identification
Screening
Eligibility
Data Abstraction
Selection & Appraisal
Additional records from supplementary searches (n = 2)
Records identified through database searching (n = 27,482)
Records after duplicates removed (n = 17,916)
Records screened (n = 17,916)
Records excluded (n = 17,842)
Full-text articles assessed for eligibility (n = 74)
Full-text articles excluded with reasons (n = 47)
Population: 6
Intervention/comparators: 28
Outcomes: 2
Study design: 4
No usable data: 6
Language: 0
Duplicate: 1
Pre-2000: 0
Additional records from bibliographies of relevant reviews (n = 10)
Studies data abstracted (n = 37)
Records excluded (n = 4)
Studies selected and appraised (n = 33)
MSM n=10
Young people n=23

Figure 2: PRISMA flowchart of included studies in the systematic review

2.4.2 Young people

The trials were generally considered to be of fair to good quality, with some exceptions. Two studies were judged to be at risk of selection bias due to poor randomisation procedures,[63, 64] two reported inadequate allocation concealment procedures,[60, 64] two had a high risk of reporting bias[53, 63] and two were high risk of attrition bias due to incomplete outcome data.[59, 63]

Several of the RCTs specifically targeted women, with 10 of the 23 studies not including men, and only a single trial limited to sexually active young men.[50] Four RCTs recruited from STI clinics[52, 55, 58, 65] with two of these trials reporting reductions in STIs[55, 58] and two were based within schools.

Four out of five video interventions designed for young people (with or without counselling) were found to be beneficial, either for reducing STIs,[57] reducing risky sexual behaviour [54, 57, 60] or increasing STI test uptake.[66] Of the three video-based interventions that reduced risky sexual behaviour, all employed behavioural skills arguments and interpersonal skills training strategies.[54, 57, 60] Three of the seven brief one-to-one counselling interventions were found to be beneficial, either for increasing STI test uptake[67] or reducing STIs,[55, 58] with both of these studies including HIV/STI testing as part of the intervention package. Four digital interventions, out of the six included, were successful in either reducing risky sexual behaviour through behavioural skills arguments or normative arguments strategies,[63, 68, 69] or increasing STI test uptake.[70] The three home testing interventions were found to be beneficial, either for increasing STI test uptake[50, 56] or reducing STIs.[59] Of the two interventions that used printed materials, one reduced risky sexual behaviour,[71] specifically unprotected sex. However, several of the studies reported no impact on either primary or secondary outcomes and may reported effects only in secondary outcomes or were underpowered to present sub-analyses.

Box 2: Intervention strategies

Definitions of intervention strategies used in this systematic review based on Albarracin's categorisation:[25]

- *Normative Arguments* **(NormA):** normative arguments about the support of condom use by friends, family members or partners; "other people are doing it; other people will approve of you doing this"
- *Attitudinal Arguments* **(AttA):** such as the discussions of the positive implications of using condoms for the health of the partners and for the romantic relationship; the pros and cons; the consequences of this behaviour will be good or bad
- *Behavioural skills arguments* **(BSA):** (what to do when partners do not want to use a condom; when recipient's or their partners are sexually excited, and when alcohol or drugs are involved) Verbal description e.g. instruction about how to put on a condom
- *Any kind of information* **(Info):** factual information (i.e. mechanisms of HIV, HIV transmission, and HIV prevention)
- *Threat-inducing arguments* **(TIA):** Such as discussions about the recipients personal risk of contracting HIV or other sexually transmitted infections (STI's)' Fear based arguments based on
    - Perceived susceptibility to a STI: "you are the type of person who will get this"
    - Perceived severity of STI: "it will harm you / you will die"
- *Condom use skills training* **(CUST):** e.g. practice with unwrapping and applying condoms
- *Interpersonal skills training* **(IST):** e.g. role playing of interpersonal conflict over condom use and initiation of discussions about protection
- *Self-management skills training* **(SMT):** self-monitor goals e.g. practice in decision making while intoxicated, avoidance of risky situations
- *STI/HIV counselling and testing* **(STI)**; involves the administration of a seropositivity test as well as the type of counselling in place

2.4.3 MSM

Overall included studies were considered to be of fair to good quality. One trial was deemed at risk of selection bias due to poor randomisation procedures,[62] and one study was at high risk of both attrition bias and detection bias due to poor blinding of outcome assessment and incomplete outcome data.[72]

Four of ten trials were limited to younger MSM, two of the studies specifically included Latino or African American men only, one addressed substance-using MSM[73] and one included only HIV-positive MSM.[62] Five out of six digital interventions designed for MSM were beneficial, either for reducing risky sexual behaviour [51, 62, 74, 75] or increasing STI test uptake.[76] There was no evidence that any of the digital interventions reduced STI incidence. Of the four digital interventions found to reduce risky sexual behaviour in MSM, all employed normative arguments and behavioural skills arguments,[51, 62, 74, 75] alongside self-management training[51, 74, 75] and information provision.[51, 74] Three of the four one-to-one counselling interventions were beneficial, either for reducing risky sexual behaviour [52, 73] or increasing STI test uptake;[72] all these included HIV/STI testing.

One study investigating a 25-minute pre-HIV test session within a clinic setting found a significant increase in the overall incidence of STIs in MSM, with higher rates amongst those who received the intervention versus control (aRR: 1.41; 95% CI: 1.05, 1.90).[52]

Table 1: Summary of Included Studies of Interventions

Young People										
Study		**Participants**		**Intervention**				**Outcomes**		
Study	**Setting**	**Number**	**Population**	**Mode of Delivery**	**Intensity**	**Duration (days)**	**Intervention Strategies***	**Outcomes**	**Effectiveness**	**Follow-up (mths)**
Shrier (2001)[60]	USA Hospital and adolescent clinic	Total=123 Intervention=60 Control=63	Women, < 24 yrs	Video, tailored 1:1 counselling, condoms & information	4 sessions (approx. 37 mins)	180	NormA, AttA, Info, BSA, TIA, CUST, IST, SMT, STI	Condom use Attitudes Knowledge	↑ condom attitude score (7.9 vs. 8.3) ↓ non-main partner (25 vs. 10%)	1, 3, 6, 12
Scholes (2003)[71]	USA Managed care settings	Total=1210 Intervention=596 Control =614	Women, 18-24 yrs	Self-help magazine & condoms; tailored feedback newsletter & condoms	2 tailored rounds	180	CP, Info, CUST	Condom use	↑ condom use any partner (aOR: 1.86, CI: 1.32, 2.65), primary partner (aOR: 1.97, CI: 1.37, 2.86)	3, 6
Booth (2014)[77]	UK School-based	Total=253 Intervention=145 Control=108	Men and women, 16-24 yrs	Short video + posters, followed by talks and repeated video	1 session (approx. 15 mins)	1	NORMA, AttA, Info, Cust	Test uptake	↑attitude to testing (aOR: 1.53, CI: 1.06, 2.22)	N/A
Cook (2007)[56]	USA Community-based setting	Total=403 Intervention=211 Control=209	Women, 15-24 yrs.	Home testing kit	Kits at 6, 12 and 18 months	540 [3]	Info	Test uptake STI	↑ testing (RR: 1.38, CI: 1.23, 1.55)	12, 24
Apoola (2011)[67]	UK Community substance misuse service	Total=54 Intervention=27 Control=27	Men and women, <20 yrs	Oral swab HIV, Hep B and C test	1 session [4]	2	STI	Test uptake	↑ testing (100% vs. 18.5% HIV testing)	N/A

Bolu (2004)[55]	USA Public STI clinics	Total=4328 Intervention=1447 Control=1443	Men and women, <25yrs	Tailored brief 1:1 counselling + HIV test counselling	2 sessions (2x20 min)	7-10	STI	STI	↓STI incidence in <20yrs (OR: 0.53, CI: 0.32, 0.86)	12
Crawford (2014)[65]	UK STI clinics	Total=212 (No. in groups not presented)	Men and women, 19-25yrs	Leaflet & tailored 1:1 by phone or face to face	1 session (up to 30 mins)	1	Info	Alcohol Condom use	No effect	6
Bull (2012)[68]	USA Online	Total=1578 Intervention=942 Control=636	Men and women, 16-25 yrs	Social media (Facebook) page	8-week content cycle	180	NormA. Info, BSA	Condom use	↑ condom use (68% vs. 56% control, at 2mths)	2, 6
Calderon (2011)[66]	USA Urban Emergency Department	Total=200 Intervention=100 Control=100	Men and women, 15-21 yrs, HIV –ve	HIV pre-test video	1 session (4 mins)	1	STI	Knowledge Testing	↑HIV knowledge score (79% vs. 66%) ↑HIV testing (51% vs 22% in control)	N/A
Chacko (2010)[53]	USA Urban reproductive health clinic	Total=376 Intervention=192 Control=184	Women, 16 - 22.5 yrs	Tailored 1:1 motivational interviewing	3 sessions (2x30-50 min; 1x15 min)	180	NormA, AttA,	Testing STI	No effect	6, 12
Downs (2004)[57]	USA Urban health centres	Total=300 (No. in groups not presented)	Women, 14-18 yrs	Video	4 sessions (1x30 min; 3x15 min)	180	Atta, Info, BSA, IST, NormA	STI Condom use Knowledge	↓STI (OR of STI in control: 2.79, p-value: 0.05) ↑ abstinence	1,3,6
Gottlieb (2004)[58]	USA STI clinics	Total=1766 (No. in groups not presented)	Men and women, 14-40yrs	Brief 1:1 general risk reduction counselling	2 sessions (20mins each)	NR	STI	STI	↓Chlamydia incident infections	3,6,9,12

Grimley (2005)[78]	USA Hospital and adolescent clinic	Total=275 Intervention=137 Control=138	Women, 14-23yrs	Tailored 1:1 session	3 sessions (15 mins each)	90	NormA, AttA, Info, BSA, SMT	Douching cessation	↓in douching (OR of stopping: 3.49, CI: 1.66, 7.32)	6,12
Kang (2012)[70]	Australia Online	Total=704 Intervention=211 Control=493	Men and women, 16-25 yrs	Personalised emails	Variable	180	Info [16]	Testing Condom use	↑ Chlamydia testing (53% vs 31%)	6
Klein (2011)[63]	USA Online	Total=178 Intervention=91 Control=87	Women, 14-19 yrs	Tailored internet-based session	2 sessions (1hr each)	1	NormA, Info, BSA, CUST, IST	Condom use Knowledge	↑ condom use (51% vs. 71%, pre-post) ↑ knowledge in both groups	3
Mevissen (2011)[69]	Netherlands Online	Total=218 Non-tailored =81 Tailored=67 Control=70	Men and women, 18-25 yrs	Tailored internet-based session	1 session	1	NormA, AttA, Info, BSA, TIA	Condom use Testing Perceptions	↑ condom use (0.88 vs. 0.43 mean)	3
				Non-tailored internet-based session	1 session	1	NormA. AttA, BSA, TIA Info	Condom use Testing Perceptions	↑ condom use (0.62 vs. 0.43 mean)	3
Metsch (2013)[52]	USA STI clinics	Total=1258 Intervention=638 Control=620	Men and women, < 25yrs	Tailored 1:1 counselling + HIV testing	1 session (20-40 mins)	1	STI, CP, Info	STI Condom use Sexual risk	↓ no. of partners (IRR: 0.76, CI: 0.69, 0.84)	6
Norton (2012)[79]	USA University of Connecticut	Total=198 HIV group=37 STI group=42 Pregnancy group=37	Men and women, >18yrs	Multi-media DVD on HIV	1 session (60 mins)	1	NormA, Info, BSA	Condom use Sexual risk	No effect vs. control	1,2
				Multi-media DVD on STIs or pregnancy	1 session (60 mins)	1	NormA, Info, BSA	Condom use Sexual risk	↑ condom use (OR: 0.19 vs. HIV)	1,2

									↓inconsistent condom use (OR: 0.42 vs. HIV)	
Ostergaard (2000)[59]	Denmark School-based	Total=5487 Intervention=2603 Control=2884	Women, 15-19yrs	Chlamydia home test kit	1 test	365	Info, STI	STI	↓ Chlamydia prevalence (2.9% vs. 6.6%)	12
Proude (2004)[64]	Australia Family practice	Total=312 Intervention=156 Control=156	Men and women, 18–25 yrs	Brief advice about safe sex & condoms	1 session	1	Info, BSA, CP	Sexual risk Perception	No effect	3
Roye (2007)[54]	USA Planned Parenthood sites	Total=400 Video=88 Counselling=81 Combined=84 Control=84	Black and Latina women, 15-21 yrs	Video & brief 1:1 counselling	1 session (40 mins)	1	BSA, TIA, IST	Condom use	↑ condom use	3,12
Scholes (2007)[50]	USA Group Health Cooperative	Total=8820 Intervention=2940 Control=2940	Men, 21-25 yrs	Home testing kit (letter & test request card)	1 session	NR	Info, STI [23]	Test uptake	↑ testing (RR: 5.6, CI: 3.6, 8.7)	4
				Home testing kit (letter & sampling kit)	1 session	NR	Info , STI [23]	Test uptake	↑ testing (RR: 11.1, CI: 7.3, 16.9)	4
Suffoletto (2013)[80]	USA Emergency department	Total=52 Intervention=23 Control=29	Women, 18-25 yrs. Hazardous drinking & risky sex	Tailored weekly risk reduction text messages	Weekly for 3 months	90	AttA, Info, , TIA, SMT	Condom use	↑ condom use (20% to 53% pre-post intervention)	3
MSM Studies										

Study	Setting	Participants	Population	Mode of Delivery	Intensity (mins)	Duration (days)	Intervention Strategies*	Outcomes	Significant findings	Follow-up (mths)
Carpenter (2010)[74]	USA Online	Total=199 Intervention=99 Control=100	MSM, 18-30 yrs	Online training modules	7 tutorials (approx. 2 hrs each)	7	AttA, Info, BSA, SMT, NormA	Condom use	↓ risky sex in both study arms	3
Coffin (2014)[73]	USA Community	Total=326 Intervention=162 Control=164	MSM, ≥ 18 yrs; Substance-use	Personalized cognitive counselling + HIV test	1 session (30-50 mins) + booster	1	STI, SMT	Sexual risks Substance use	↓ unprotected receptive anal sex (RR = 0.57, CI: 0.33, 1.01)	3,6
Hirshfield (2012)[81]	USA Online	Total=3092 Video=1874 Webpage=609 Control=609	MSM, 18-81 yrs	Internet-based video and HIV prevention information	Videos 9 and 5 mins	1	BSA, SMT	Test uptake Condom use	↓ unprotected anal sex (OR = 0.61, CI: 0.48, 0.77)	2
					Webpage	1	Info	Test uptake Condom use	↓ unprotected anal sex (OR = 0.42, CI: 0.27, 0.66)	2
Metcalf (2005)[61]	USA Public STI clinics	Total=138 Intervention=70 Control=68	MSM, 15-39 yrs .	Brief 1:1 counselling	2 sessions + booster (20 mins)	180	STI, SMT	STI Sexual risk	No effect	3,6,9,12
Metsch (2013)[52]	USA STI clinics	Total =1074 Intervention=529 Control=545	MSM, ≥ 18 yrs	Tailored 1:1 counselling + HIV testing	1 session (20-40 mins)	1	STI, CP, Info	STI Condom use Sexual risk	↑ STI incidence in intervention group (aRR: 1.41, CI: 1.05, 1.90) ↓ unprotected sex (IRR: 0.71, CI: 0.61, 0.83)	6

Milam (2014)[62]	USA University clinical sites	Total=179 Intervention=90 Control=89	HIV-infected MSM, >18 yrs	Internet-based tailored messaging	Monthly messages	360	NormA, BSA	STI Condom use	↓ unprotected sex in both study arms	Monthly (1 -12 months)
Mustanski (2013)[51]	USA Online	Total=102 Intervention= 50 Control=52	HIV-negative MSM, 18-24 yrs	'KUI!' 3 online modules	2 hrs	90	NormA, AttA, Info, BSA, SMT	Condom use HIV attitude	↓ unprotected anal sex at 3 months (RR: 0.56)	1.5, 3
Outlaw (2010)[72]	USA Community services	Total=188 Intervention=96; Control=92	African American MSM, 18-26 yrrs	Community motivational interviewing + HIV testing	30 minutes	7 -10	STI, CP	Test uptake	↑ HIV testing (49% vs. 20%)	N/A
Rosser (2010)[75]	USA Online	Total=650 Intervention=337 Control=313	MISM, >18 yrs	'Sexpulse' webpage	Completed 7 days after enrolment	1	NormA, BSA, SMT	Condom use	↓ unprotected anal sex at 3 months (aRR: 0.84, CI: 0.70, 1.01)	3,6,9,12
Young (2013)[76]	USA Online	Total=112 Intervention=57 Control=55	African American and Latino MSM, >18 yrs	Social media (Facebook) page and home-testing	Kit offered every 4 weeks	90	STI, Info	Test uptake Condom use	↑ HIV testing (44% vs. 20%)	3

Notes: CG = control group; NR = not reported; OR = odds ration; STI = sexually transmitted infection; MISM = men who use the internet to seek sex with men; RR = relative risk

* **NormA** (Normative Arguments); **AttA** (Attitudinal Arguments); I**nfo** (Any kind of Information); **BSA** (Behavioural Skills Arguments); **TIA** (Threat-inducing Arguments); **CUST** (Condom Use Skills Training); **IST** (Interpersonal Skills Training); **SMT** Self-Management Training; **STI** (STI/HIV Counselling and Testing)

2.5 Discussion

We found 33 RCTs that met our inclusion criteria of evaluating a brief behavioural intervention for improving sexual health outcomes amongst young people and MSM. A number of interventions trialled were effective at improving testing, reducing self-reported risk behaviours (such as condomless sex) and decreasing STI diagnoses (Table 2). However, the effect sizes seen were generally small, the types of interventions and outcomes evaluated highlight that there is still a lack of evidence for certain approaches to improving sexual health behaviours, and one study demonstrated a negative intervention impact.

Table 2: Summary of Intervention Effectiveness

Intervention	**Young People (n=23)**			**MSM (n=10)**		
	No. of trials	Effective trials	Improved outcome	No. of trials	Effective trials	Improved outcome
Digital	6	3	RSB Test	6	4 1	RSB Test
One-to-one counselling	7	2	STI Test	4	2 1	RSB Test
Video	5	3 1 1	RSB STI Test			
Printed materials	2	1	RSB			
Home test kit	3	1 2	STI Test			
RSB = risky sexual behaviour; Test = STI test uptake; STI = STI incidence						

2.5.1 Reducing sexual risk behaviours

The majority of trials in both young people and MSM populations involved either digital interventions or one-to-one counselling. Digital interventions were found to be effective for reducing risky sexual behaviour in half of the trials for young people, and in two thirds of MSM studies. The successful digital interventions in both young people and MSM employed normative arguments and behavioural skills arguments.[51, 62, 63, 68, 69, 74, 75] In addition, successful digital interventions in both high risk populations employed information in five trials[51, 63, 68, 69, 74] and self-management skills training in three

trials.[51, 74, 75] Successful interventions provided most or all of the following: arguments about the support of condom use by friends, family members or partners; information about STIs, such as prevalence, transmission, and details on how to reduce the risk for transmission; help in identifying personal risk for STIs; training in common behaviour change processes, such as problem solving, decision making, and goal setting; and training in communication surrounding condom use and safe sex.

Two of four trials of one-to-one counselling showed improvement in risky sexual behaviour for MSM, while none of the seven trials of one-to-one counselling in young people were found this to be effective for this outcome. Although the sample of studies is too small to draw statistical inferences this could indicate a difference between the two groups regarding effectiveness of these interventions on risky sexual health behaviour, with MSM appearing to respond better to both one–to-one counselling and digital interventions than young people. However, the difference in effectiveness may be related to the nature of the intervention strategies employed. While both normative arguments and behavioural skills training were successfully employed in digital interventions for both MSM and young people to reduce risky sexual behaviour, the successful digital interventions for MSM also used information and self-management skills training (in addition to normative arguments and behavioural skills arguments), and this may have accounted for their success.

Video interventions were effective for reducing risky sexual behaviour in three out of the five RCTs, and those that were successful contained behavioural skills training and interpersonal skills training, and two used threat-inducing arguments.[54, 57, 60] One intervention involving printed materials was successful in reducing sexual behaviour in young people, using condom provision, information and condom use skills training.[71]

However, both the video and printed material interventions were only conducted in young people, with no RCTs involving either conventional (non-online) videos or printed materials targeting MSM. This presents a potential opportunity for developing interventions involving video and printed materials tailored to a MSM population to reduce risky sexual behaviour. However, it should be noted that one MSM trial used a video format within an online digital intervention, and this was not found to be effective for any of the outcomes of interest in our review.

2.5.2 Reducing STI incidence

None of the MSM interventions reported success in reducing STI diagnoses. Both of the one-to-one interventions that reduced incidence of STIs in young people consisted of a brief counselling session

plus a HIV/STI test,[55, 58] while one-to-one counselling did not reduce STIs in any of the four trials conducted with MSM.

One out of five trials of video interventions aimed at young people showed an improvement in STIs, employing attitudinal arguments, information, behavioural skills training and interpersonal skills training.[57] One out of three trials of home test kits showed an improvement in STIs in young people, delivering information alongside the test kit.[59] Again, neither of these intervention formats were trialled in MSM populations.

2.5.3 Increasing STI testing

For digital interventions, one MSM and one young person's trial increased STI test uptake.[70, 76] Successful interventions provided information including information about testing, one being personalised advice through email. Similar findings were observed for one-to-one counselling, with only one trial for young people and one trial for MSM being found to be effective for increasing STI test uptake, which both included oral swab tests.[67, 72] In video interventions developed for young people, one of five trials was effective for increasing STI test uptake; the successful video was specifically designed to replace one-to-one counselling before an HIV test.[66]

More promising however were interventions involving home test kits. Two of the three trials using this methodology effectively increased testing, and both included information and instructions on using the test kit.[50, 56] It is notable that no RCTs involving home test kits were found for MSM, suggesting a potential opportunity for developing such interventions tailored to a MSM population. **Table 3** summarises the successful strategies used within RCTs that showed evidence for improved outcomes, and strategies for which there was weaker evidence (potential strategies).

Table 3: Summary of Features Associated with Programme Effectiveness

Outcome	**Intervention**	**Successful strategies**		**Potential strategies**	
		Young people	**MSM**	**Young people**	**MSM**
Reduce risky sexual behaviour	**Counselling**		HIV/STI testing		
	Digital	NormA, BSA	NormA, BSA		SMT, Info
	Video	BSA, IST		TIA, AttA, info	
	Home test kit				

	Printed materials			CP, info, CUST	
Reduce STI incidence	**Counselling**	HIV/STI testing			
	Digital				
	Video	Atta, Info, BSA, IST			
	Home test kit			HIV/STI testing	
	Printed materials				
Increase STI test uptake	**Counselling**	HIV/STI testing	HIV/STI testing		
	Digital	Info	Info		
	Video	HIV/STI testing			
	Home test kit	Info			
	Printed materials				
NormA: Normative Arguments; AttA: Attitudinal Arguments; Info: Any kind of Information; BSA: Behavioural Skills Arguments; TIA: Threat-inducing Arguments; CUST: Condom Use Skills Training; IST: Interpersonal Skills Training; SMT: Self-Management Training; HIV/STI testing: STI/HIV Counselling and Testing.					

2.5.4 Recommendations for intervention development

Existing evidence suggests that digital interventions for both MSM and young people should contain normative arguments, behavioural skills training and information in order to maximise impact on risky sexual behaviour and STI test uptake. In addition, self-management skills training may be usefully employed to reduce risky sexual behaviour. One-to-one counselling interventions for both MSM and young people should contain HIV/STI testing as part of the intervention, with trials to date showing this can increase STI testing, reduce STIs and reduce risky sexual behaviour. However, these interventions have not been widely evaluated in different geographical and demographic populations, so some caution is needed in assuming that these benefits will be realised in this population.

There was more evidence for diverse intervention formats amongst young people, and video-based interventions also containing behavioural skills training, interpersonal skills training, attitudinal arguments, information and HIV/STI testing could improve risky sexual behaviour, STIs and STI test uptake. Additionally, threat-inducing arguments, attitudinal arguments and information may be usefully employed to reduce risky sexual behaviour. Home testing kits should contain information in order to improve STI test uptake, and the act of testing may be usefully employed to reduce STIs.

Given the lack of RCTs identified in this systematic review for conventional (non-online) video interventions, home test kits and printed materials for the MSM population, opportunities exist for developing such interventions. We would cautiously recommend using the strategy components described above in any new intervention design for MSM, while accepting the need for further adaptation and piloting.

2.5.5 Challenges for intervention adaptation

Many of the successful interventions were tailored to gender or ethnicity groups, with half of the young people studies targeting Latina or African American women. Therefore, taking these interventions out of this cultural and demographic context may change both their efficacy and acceptability. This is particularly a challenge for the young heterosexual male group, as very few interventions were designed specifically for this group. Interventions such as Roye et al.[54] were designed with input from the specific patient group it was targeting (i.e. young African American women), which makes it less likely to be appropriate as an 'off the peg' intervention for use in the UK. So while several interventions may be desirable or acceptable in principle, we anticipate that considerable adaptation may be needed.

Metsch et al. (2013)[52] found an increase in STI incidence amongst MSM in the 1:1 pre-HIV testing intervention group (12.5% control vs. 18.7% intervention). Conflicting efficacy within intervention formats or between sub-groups, such as MSM or young people, could lead to negative results when adapted to a different context or setting.

2.5.6 Strengths and limitations

A key strength of this review is that it began with a broad search for RCTs of behavioural interventions in both young people and MSM. However, despite the extensiveness of the search, with over 17,000 articles screened, young heterosexual males were found to be under-represented in the literature with only one RCT focused exclusively on this group.[50] This could represent a publication bias, or be a lack of research into this particular risk group. Several of the RCTs did not assess STI outcomes, but reported risk behaviours as the primary outcome. The outcomes are self-reported and could suffer from social desirability bias, and therefore should be interpreted with caution. In addition, several of the studies reported on multiple secondary outcomes, and lacked power to assess these and did not account for multiple hypothesis testing.[82] This may have resulted in some of the weak statistical associations observed. However, it also poses the potential for interventions presented for adaptation

and scale-up to have modest effects. We included studies in the review which showed no effect, allowing us to examine whether there was consistent evidence for an intervention format or strategy being successful or not.

The diverse range of settings in which the RCTs were performed could have influenced our conclusions. The quality and availability of resources, such as counselling, which are routinely offered could affect the efficacy of the trials; when usual care is extremely minimal, a relatively brief intervention might improve on it enough to show a benefit. While other settings, where routine care is more comprehensive, may show a smaller effect or no effect at all. This limits the generalisations we can make, particularly for the MSM studies which were all conducted in the USA.

Many of the RCTs identified in this review use specific gender and ethnic samples, and the diversity of these groups must also be taken into account when considering generalizability of the review findings. For example, one study was restricted to HIV-positive MSM, who may react different to intervention approaches than HIV-negative MSM.[62] We found very few studies conducted in the UK, and only one within a UK sexual health setting.

Length of follow-up may have resulted in the apparent lack of impact seen on some sexual behavioural outcomes. It was notable that some interventions showed short-term improvement in outcomes, which was not seen later in the follow-up period.[54, 68, 75] This is confirmed by other evidence that suggests that the effect associated with an intervention may diminish with time after intervention delivery.[83, 84] Therefore, our assessment may have excluded potentially effective intervention approaches, but which lacked longer term impacts. Such approaches might be effective in the longer term if repeatable.

2.6 Conclusion

A number of interventions have the potential to be adapted for use in routine sexual health settings within the UK were identified. Intervention formats, such as videos, self-testing kits, one-to-one counselling sessions, and various forms of digital interventions (e.g. social media and emails) could all be appropriate candidates, and showed limited but significant effectiveness in increasing testing, reducing risk behaviours, and reducing STIs. Despite the diversity of the interventions, there were common themes within the successful interventions, such as using behavioural skills arguments that can be used to guide intervention adaptation.

Chapter 3: Work Package 2 - Triage Tool Development

3.1 Background

The use of data driven triage tools, developed using predictive statistical models, is relatively common in both primary and secondary clinical care.[85] They are used to target individual care, based on key risk characteristics found at the population level, such as the Framingham risk score which has been widely used to support treatment decisions for cardiovascular disease.[86] In sexual health, triage is commonplace.[87, 88] Clinics often stratify patients according to symptoms, behavioural risks and demographics to receive different services, such as 'quick checks' or safe-guarding.[89, 90] These triage processes tend to be a dichotomous decision based on pre-defined criteria, which may not necessarily take into account risk behaviours or identify patients most in need of interventions.[91]

Since 2009, SH clinics in England have provided data to a mandated surveillance system for sexual health episodes, the Genito-Urinary Medicine Clinic Activity Dataset (GUMCAD).[92, 93] This dataset contains 12 variables that include demographics and any tests and diagnoses related to that episode of care. This has allowed spatial trends in STIs to be monitored over time; however it lacks information on risk behaviours, which would allow for more detailed risk stratification.

In order to facilitate a more in-depth understanding of STI epidemiology in England, Public Health England (PHE) enhanced the GUMCAD dataset to include numbers of partners, drug and alcohol use, prior GUM clinic visits and partner notifications in GUMCADv3.[94, 95] These variables are all recommended to be recorded as part of a patient consultation by BASHH, and are therefore intended to be feasible for collection in routine care.[96] The GUMCADv3 reporting system was piloted in two phases, with revisions made in phase 2 based on clinic feedback and data quality issues from phase 1.

A population-level data-driven approach to triage, based on the risk of a STI diagnosis, has not yet been applied to the UK setting. In order to test a model of delivery of a behavioural intervention that is tailored to the risk profile and characteristics of the target population we therefore developed a data-driven triage tool that could be integrated into service systems and processes.

3.2 Aim

To develop a triage tool, based on clinical data routinely collected within SH clinics in England, to stratify patients according to their risk of STI diagnosis and thereby direct service users to tailored behavioural interventions individualised to their needs. Separate models were to be developed for the

MSM and young people groups, due to the different risk types and relative importance of behavioural and demographic data.

3.3 Method

We conducted secondary data analysis of the nationally mandated GUMCADv2 data from 2013-2015 and the second phase of the GUMCADv3 pilot, conducted in 2015-2016. Analysis of the Phase 1 GUMCADv3 pilot is not presented as this version of the surveillance system was superseded by the Phase 2 version.

3.3.1 Datasets

Surveillance (GUMCADv2): This is a national mandatory reporting dataset for England, which all level-2 and level-3 SH services are required to submit their sexual health patient episodes to PHE. It covers an estimated 600 services and reports STI diagnoses and sexual health services provided. The dataset contains 12 variables (**Table 4**): demographics, attendance information and any episode activity and diagnoses. Data from the reporting periods Q1 2013 – Q3 2016 were used. This dataset is referred to as 'v2' throughout.

Enhanced surveillance (GUMCADv3 Pilot 2): This dataset was generated by PHE during a pilot conducted from July 2015 –June 2016 in five SH clinics: Bedford (Brook), Bristol (GUM), Croydon (GUM), Barnet (GUM) and Southend (GUM). This dataset contains the same 12 variables from v2 and an additional 18 questions on recent sexual behaviours, drug and alcohol use, and previous diagnoses and attendance (Table 4). This dataset will be referred to as 'v3p2' throughout.

Table 4: GUMCAD variables available for triage tool analysis

Surveillance	
Question	**Format**
Gender	Categorical
Age at attendance *(derived from date of birth)*	Continuous
Self-defined ethnicity	Categorical
Country of birth	Categorical
Deprivation index *(derived from Lower layer super output area of residence)*	Continuous

Self-identified sexual orientation	Categorical
SHHAPT or READ codes of the diagnoses and/or service received	Categorical
Enhanced Surveillance	
Question	**Format**
Number of partners in the last 3 months?	Categorical
How many were new partners? *(heterosexual and WSW only)*	Categorical
Did you/your partner use a condom the last time you had penetrative (vaginal or anal) sex? *(heterosexual only)*	Categorical
Have you had anal (receptive or insertive) sex with a known HIV positive partner in the last 3 months? *(MSM only)*	Categorical
Have you had any condomless anal sex (receptive or insertive) in the last 3 months? *(MSM only)*	Categorical
Have you had any receptive condomless anal intercourse in the last 3 months? *(MSM only)*	Categorical
Was alcohol use assessed?	Categorical
Was alcohol use documented as problematic?	Categorical
Have you used recreational drugs in the last 3 months?	Categorical
Did you take: amphetamine/speed; benzodiazepines; cannabis; cocaine; crack; crystal meth; E/MDMA; GBH/GBL; heroin; ketamine; legal highs; m-cat; methadone; poppers; solvents/glue; other	Binary (yes)
Did you inject any recreational drug in the last 3 months?	Categorical
Did you share equipment with anyone when injecting drugs?	Categorical
Were you under the influence of recreational drugs (before or during sex) the last time you had sexual intercourse?	Categorical
Have you ever attended another GUM service?	Categorical
Have you been diagnosed with an STI in the last year?	Categorical
Did you have: chlamydia; gonorrhoea; herpes; LGV; non-specific genital; syphilis; warts; other	Binary (yes)
When did you last have an HIV test?	Categorical

Het = heterosexual; msm = men who have sex with men; wsw = women who have sex with women

3.3.2 Definitions

Young person: Any attendance amongst all women, and men who have no report of sex with men and self-reported as heterosexual, aged 16-25 years old.

MSM: Any attendance amongst men who have any report of sex with men, or self-report as bisexual or homosexual, of any age.

Attendance: Any first attendance within an episode of care

Outcome: any new diagnosis of HIV, syphilis, gonorrhoea, chlamydia, hepatitis, LGV, trichomonas or herpes. Recurrent herpes and warts infections and non-specific genital infections were excluded.

3.3.3 Data Management

The v2 data undergoes routine data cleaning processes by PHE; details of this process are available on request from PHE ('GUMCADv2 Specifications Manual_v3_23_09_2014'). The v3 data was cleaned for inconsistencies between demographic and reported sexual behaviours (e.g. female heterosexual reported as having female sex partners), drugs reports (e.g. no reported drug use and sharing injecting equipment) and previous sexual health attendances and diagnoses. During the cleaning, any positive answer to a risk behaviour was prioritised during cleaning, for example a patient reported 'no' to drug use in the prior 3-months but reports yes to using cannabis in subsequent questions. In this case, 'any drug use' would be changed to 'yes', and cannabis use unchanged. For discrepancies between gender, sexual orientation and types of partners, gender and partner type were prioritised. For example, male, heterosexual, reporting male partners would be classified as MSM within the model. Cases with multiple pieces of conflicting data were excluded.

The core v2 variables were still reported through the routine v2 system for the pilot clinics; the v3 pilot data was submitted separately to PHE. The clinic code, patient ID and attendance date were used to merge the two datasets. Checks for discrepancies in demographic information between v2 and v3 datasets were conducted, and resolved on a case by case basis – and cases with inconclusive cleaning were excluded from analysis. Comparing demographic variables between patients from the v3p2 who merged with a v2 record was done to test for possible biases in the sub-set of patients available for analysis. All cleaning, merging and data management was done using Stata version 13.[97]

3.3.4 Selection of candidate predictors

The predictor variables investigated were those available in the dataset. The behavioural and risk variables included in the v3p2 dataset were based on those recommended for sexual history taking by BASHH in 2013 and are well supported in the literature as being indicators of STI risk.[96] The variables were split into demographic and behavioural variables. Demographics variables included: age, deprivation, prior GUM visits, prior STI diagnosis (including specific infections), ethnicity, country of birth, sexual orientation, and gender and HIV status. Behavioural variables included: number of sexual partners, new partners, condom use, problematic alcohol use and drug use, and unprotected anal intercourse (UAI) and sex with known HIV positive partners in MSM. Depending on the number of observations and degrees of freedom in the models, variables were re-categorized between models.

All these variables were considered in the model development; however, exclusions due to missing data and low prevalence (e.g. <5%) were done following initial description. Variables with missing data may introduce bias if the data is not missing at random (e.g. if patients are less likely to disclose risky behaviours, or differences in reporting quality between clinics), and if they are not frequently available then including them in a triage tool might be impractical.[98] There are several approaches to dealing with missing data. For variables with limited missing data (<25%), which are assumed to be missing at random, multiple imputation is recommended as it preserves sample size.[99] However, including missing data as a distinct category may be a more pragmatic approach as complete data collection within a routine clinical setting may not be realistic, and missing data is unlikely to be missing completely at random. This was our primary analysis approach.

To protect against over-fitting, a general rule is to have 10 outcome events (i.e. STI diagnoses) per degree of freedom in the development model (i.e. predictor variable).[100] Lower-priority or highly correlated candidate predictors were removed to reduce degrees of freedom where possible and needed.[100]

3.3.5 Developing the prediction model

The primary outcome was the binary composite variable of STI diagnosis. Multi-variable logistic regression was used to develop the triage tool. The primary models were developed in the v3p2 dataset, one for MSM and one for young people.

We used a full model approach, with all pre-defined variables included regardless of statistical association in univariate analysis.[98, 101] We conducted a sensitivity analysis using a forward stepwise approach to explore whether a more parsimonious model could be used. All variables were binary or categorical, except age and deprivation score (derived from the patient's postcode). Continuous

variables were investigated for non-linear relationships with the outcome, and categorised if appropriate. Data reduction within the categorical variables (e.g. ethnicity) was done based on data patterns and substantive knowledge.

The regression coefficients were used to calculate an individual's probability of STI diagnosis, using the following equations (**Box 3** presents a worked example):

EQ1: Log odds of STI = model intercept + (variable value x coefficient) +….

EQ2: Patient's Odds of STI = $e^{(\text{patient's log odds value})}$

EQ3: Probability of STI = [Odds / (1 + Odds)] x 100

3.3.6 Model performance

Model performance was evaluated using several statistical tests. The Hosmer-Lemeshow goodness of fit test was done to measure model calibration,[102] despite its limitations.[103] Model discrimination was tested using the c-statistic (area under the receiver operating characteristic curve (AUROC)).[98, 104] The c-statistic and the pseudo R^2 were the main parameters for determining if the model was effective at predicting the outcome of interest. A c-statistic of >0.7 is generally considered reasonable model discrimination for a clinical tool, and >0.8 as strong discrimination; 0.5 indicates that the model is no better than chance at predicting the outcome.[105] The Bayesian Information Criteria (BIC) was used to determine the most parsimonious model in sensitivity analyses, with lower values favouring model selection.

We compared different probability thresholds with the patient's true outcome, to give sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV). External validation, where the regression equation is tested in a district dataset is recommended as an independent assessment of the model performance to assess the extent of over-fitting and the resulting optimism of its performance.[106] External validation was not conducted due to the limited sample size of the v3p2 pilot; however it was discussed that external validation could done as part of the WP5 (Chapter 6) pilot implementation.

3.3.7 Sensitivity analyses

We conducted sensitivity analyses in order to test assumptions about our primary modelling approach. We assessed a model which only included demographic data to determine how much added value the additional behavioural information provides; this also allowed us to investigate whether

demographics at the national level had different relationship directions and magnitude of effect to the smaller v3p2 dataset. Missing data, which was included as a distinct category in the primary model, was compared to imputed models to gives us more information on pragmatic implementation. Taking a categorised missing approach was done to reflect the real-world nature of routine data, and as we made the assumption that data was not missing at random and therefore may contain predictive value in itself. Finally, a full model, where all a priori defined variables were included was compared to a forward stepwise regression to approach.

3.4 Results

3.4.1 Data description

During the pilot period from July 2015 to June 2016, a total of 28,514 episodes of care were reported. **Table 5** describes the key demographic variables, between those with and without enhanced behavioural data. The patients recorded in the v3p2 dataset were similar in terms of ethnicity, age and gender to those with basic surveillance only for the same time period. There was considerably higher levels of missing sexual orientation in the enhanced dataset (16% vs. 7%), and lower levels of homosexual or bisexual patients (6% vs. 13%). This likely reflects the pilot sites not including any of the larger MSM clinics, such as Dean Street or Brighton.

Following cleaning of the merged dataset, there were 9,530 non-MSM young people recorded in the v3p2 pilot, of which 1,005 had an STI diagnosis (10.6%). This is very similar to the STI diagnosis rate seen in the national surveillance dataset during the same time period (10.8%). There were 1,448 MSM records in the v3p2 dataset, with 318 STI diagnoses (22.0%). This was higher than the nationally reported rate of 14.9%. This allows up to 100 and 32 degrees of freedom in the young person and MSM models to avoid over-fitting.

Table 5: Description of demographic variables in the GUMCAD surveillance and enhanced surveillance datasets

Variables		Enhanced surveillance (N, %) N = 23,107		Surveillance only (N, %) N = 5,407	
Gender	Male	9,419	(41%)	2252	(42%)
	Female	13,613	(59%)	3155	(58%)
	Missing	3	(0%)		
Sexual Orientation	Heterosexual	17,761	(77%)	4,314	(80%)
	Bisexual	1.034	(4%)	493	(9%)
	Homosexual	540	(2%)	202	(4%)
	Missing	3,772	(16%)	398	(7%)
Ethnicity	White	16,197	(70%)	3,544	(66%)
	Asian	1,124	(5%)	282	(5%)
	Black	3,732	(16%)	967	(18%)
	Mixed	1,374	(6%)	374	(7%)
	Other	233	(1%)	49	(1%)
	Missing	447	(2%)	191	(4%)
Age	<25 years	8,990	(39%)	1,781	(33%)
	25-34 years	8,665	(38%)	1,964	(36%)
	35-44 years	3,293	(14%)	898	(17%)
	45-64 years	2,007	(9%)	696	(13%)
	>=65 years	151	(1%)	68	(1%)

Young people and MSM differed from the general surveillance population, and from each other (**Table 6**). There were more young women than men, compared to the general clinic population (69% versus 59% female). The MSM group were generally older than the overall clinic population, and more likely to be of White ethnicity (70% versus 82%). The number of partners reported by young people generally reflected the general population, but MSM reported a higher proportion of multiple partners, with 15% reporting five or more partners in the previous 3-months compared to 3% of the general pilot clinic population. They also had a lower level of missing data for this variable. MSM had double the rate of drug use reported compared to young people (14% versus 7%) and considerably lower rates of missing data for this variable (31% versus 52%). This supports the assumption that data was unlikely to be missing at random, with either MSM being more likely to disclose drug use, or providers being more likely to ask about drug use with MSM patients.

Table 6: Description of GUMCAD enhanced surveillance data

Variables		Total (N, %) N = 23,103	Young people (N, %) N = 9,530	MSM (N, %) N = 1,448
Demographic Variables				
Gender	Male	9,491 (41%)	2,983 (31%)	1,448 (100%)
	Female	13,612 (59%)	6,547 (69%)	-
Age	<20 years	2,938 (13%)	2,628 (18%)	77 (5%)
	20 – 24 years	6,052 (26%)	6,902 (82%)	297 (21%)
	25 – 34 years	8,664 (38%)	-	562 (39%)
	35 – 44 years	3,291 (14%)	-	262 (18%)
	45 – 64 years	2,007 (9%)	-	213 (15%)
	>= 65 years	151 (1%)	-	37 (3%)
*Sexual Orientation	Heterosexual	17,758 (77%)	7,809 (82%)	51 (4%)
	Bisexual	540 (2%)	120 (1%)	299 (21%)
	Homosexual	1,034 (4%)	27 (0%)	963 (67%)
	Missing	3,771 (16%)	1,574 (17%)	135 (9%)
Continent of birth	UK	15,682 (68%)	6,813 (71%)	1,049 (72%)
	Europe	2,095 (9%)	643 (7%)	153 (11%)
	Africa	1,134 (5%)	309 (3%)	40 (3%)
	Americas	821 (4%)	217 (2%)	43 (3%)
	Asia	289 (1%)	51 (1%)	19 (1%)
	Other	618 (3%)	190 (2%)	54 (4%)
	Missing	2,464 (11%)	1,307 (14%)	90 (6%)
Ethnicity	White British	13,639 (59%)	6,072 (64%)	1,003 (69%)
	Other White	2,554 (11%)	785 (8%)	185 (13%)
	South Asian	661 (3%)	201 (2%)	33 (2%)
	Other Asian	463 (2%)	165 (2%)	36 (2%)
	Black Caribbean	1,353 (6%)	448 (5%)	28 (2%)
	Other Black	2,379 (10%)	991 (10%)	54 (4%)
	White & Black mixed	826 (4%)	418 (4%)	31 (2%)
	Other Mixed	548 (2%)	249 (3%)	38 (3%)
	Any Other	233 (1%)	79 (1%)	17 (1%)
	Missing	447 (2%)	122 (1%)	23 (2%)
Deprivation quintiles	Lowest	4,731 (20%)	1,744 (18%)	294 (20%)
	2nd quintile	6,019 (26%)	2,364 (25%)	354 (24%)
	3rd quintile	4,257 (18%)	1,768 (19%)	259 (18%)

	4th quintile	4,291 (19%)	1,937 (20%)	273 (19%)
	Highest	2,917 (13%)	1,363 (14%)	213 (15%)
	Missing	888 (4%)	354 (4%)	55 (4%)
**Previous STI diagnosis	No	21,526 (93%)	8,795 (92%)	1,329 (92%)
	Yes	1,577 (7%)	735 (8%)	119 (8%)
Behavioural Variables				
Number of partners+	None	1,068 (5%)	365 (4%)	73 (5%)
	1 partner	10,893 (47%)	4,336 (46%)	410 (28%)
	2-4 partners	4,037 (17%)	1,660 (17%)	506 (35%)
	>= 5 partners	649 (3%)	206 (2%)	215 (15%)
	Missing	6,456 (28%)	2,963 (31%)	244 (17%)
New partners+	No		2,658 (28%)	-
	Yes		2,663 (28%)	-
	Missing		4,209 (44%)	-
Condom use last sex	No		3,881 (41%)	-
	Yes		2,014 (21%)	-
	Missing		3,635 (38%)	-
Anal sex with known HIV +ve+	No		-	786 (54%)
	Yes		-	124 (9%)
	Missing		-	538 (37%)
Condomless anal sex+	No		-	419 (29%)
	Yes		-	535 (37%)
	Missing		-	494 (34%)
Receptive condomless anal sex+	No		-	138 (10%)
	Yes		-	350 (24%)
	Missing		-	960 (66%)
Problematic alcohol use	No	4,558 (20%)	1,890 (20%)	192 (13%)
	Yes	203 (1%)	102 (1%)	22 (2%)
	Missing	18,342 (79%)	7,538 (79%)	1,234 (85%)
Drug use+	No	10,212 (44%)	3,860 (41%)	795 (55%)
	Yes	1,537 (7%)	686 (7%)	199 (14%)
	Missing	11,354 (49%)	4,984 (52%)	454 (31%)

**These relate to females only in the young people, and in the MSM, self-reported heterosexuals who reported same sex male partners were included in the MSM group; **within the previous 12 months; + within the previous 3 months.*

3.4.2 Young person model

Variable selection

Deprivation was included as quintiles, based on the UK indices of multiple deprivation derived from the patient's postcode. Age was included in the model as a categorical variable; plotting the relationship between age and STI diagnosis showed the association was not linear. We described the number of prior STI diagnoses reported, both longitudinally and from patient report. Within this cohort of young people, there were very few non-chlamydia prior diagnoses and therefore we included prior chlamydia infection only in the model. Ethnicity and continent of birth contain a large number of categories, 15 and 9 respectively, adding 23 degrees of freedom to the model. Many of the categories contained <5% of the patient population; therefore, these variable categories were collapsed to ensure more balanced categories for modelling. Drug use and problematic alcohol use were excluded due to high levels of missing data, and sexual orientation excluded for having too little heterogeneity.

Table 7 describes the variables and categories that were included in the primary analysis.

Table 7: Variables and their definitions in the primary young person's model

Demographic	
Gender	Male (reference), Female
Ethnicity	White (reference), White other, S. Asian, Asian other, Black Caribbean, Black other, White and black mixed, Mixed other, Other, Missing
Continent of birth	UK (reference), Europe, Africa, Americas, Asia, Other, Missing
Prior Chlamydia diagnosis	No (reference), Yes – within the last year
Age	16-17 (reference), 18-19, 20-21, 22-23, 24-25 years
Deprivation score	Quintiles – least deprived (reference)
Behavioural	
Number of partners	None (reference), One, Two – Four, Five or more, Missing
New partners	No (reference), Yes, Missing
Condom use	No (reference), Yes, Missing

Primary model

The primary model categorized missing data, retaining all records in the model (**Table 8**). The model included 34 degrees of freedom, and therefore met the required 10 outcomes per degree of freedom. Amongst YP, females were less likely to have an STI diagnosis (OR: 0.71, 95% CI: 0.62, 0.83), and being older was associated with lower odds of STI diagnosis. Being of black or mixed white and black ethnicity had higher odds of STI diagnosis, compared to being white British.

Table 8: Full multivariable logistic regression model for STI diagnosis in the current visit in YP

Variable		Odds ratio	Coefficient	p-value	95% confidence interval	
Gender	Male	1.00				
	Female	***0.71***	***-0.34***	***0.000***	***0.62***	***0.83***
Ethnicity	White British	1.00				
	White, other	1.33	0.28	0.099	0.95	1.86
	South Asian	0.73	-0.32	0.308	0.39	1.35
	Asian, other	0.94	-0.06	0.854	0.49	1.80
	Black Caribbean	***2.65***	***0.98***	***0.000***	***2.01***	***3.50***
	Black, other	***1.57***	***0.45***	***0.000***	***1.25***	***1.97***
	White & black mixed	***1.85***	***0.61***	***0.000***	***1.39***	***2.45***
	Mixed, other	0.88	-0.13	0.596	0.55	1.41
	Other	0.69	-0.37	0.409	0.29	1.66
	Missing	0.85	-0.16	0.661	0.42	1.73
Continent of birth	UK	1.00				
	Europe	1.03	0.03	0.881	0.72	1.47
	Africa	***0.66***	***-0.42***	***0.046***	***0.44***	***0.99***
	Americas	0.77	-0.26	0.234	0.50	1.18
	Asia	0.42	-0.86	0.262	0.09	1.90
	Other	0.89	-0.12	0.695	0.48	1.62
	Missing	***0.78***	***-0.24***	***0.033***	***0.62***	***0.98***
Age	16-17 years	1.00				
	18-19 years	***0.77***	***-0.26***	***0.050***	***0.59***	***1.00***
	20-21 years	0.81	-0.21	0.107	0.63	1.05
	22-23 years	***0.70***	***-0.36***	***0.006***	***0.54***	***0.90***
	24-25 years	***0.62***	***-0.48***	***0.000***	***0.48***	***0.80***
Deprivation	Quintile 1 (highest)	1.00				
	Quintile 2 (high)	0.91	-0.10	0.325	0.74	1.10
	Quintile 3 (medium)	1.00	-0.004	0.973	0.80	1.24
	Quintile 4 (low)	0.84	-0.18	0.126	0.67	1.05
	Quintile 5 (lowest)	0.80	-0.23	0.090	0.61	1.04
	Missing	1.14	0.13	0.464	0.80	1.61
Previous Chlamydia	No	1.00				
	Yes	***3.66***	***1.30***	***0.000***	***2.88***	***4.65***
Number of partners	0 partners	1.00				
	1 partner	***2.16***	***0.77***	***0.011***	***1.19***	***3.91***
	2-4 partners	***2.51***	***0.92***	***0.003***	***1.36***	***4.64***

	>= 5 partners	***2.58***	***0.95***	***0.008***	***1.28***	***5.22***
	Missing	1.49	0.40	0.149	0.87	2.57
New partners	No	1.00				
	Yes	***1.45***	***0.37***	***0.000***	***1.19***	***1.77***
	Missing	***1.89***	***0.64***	***0.000***	***1.38***	***2.60***
Condom use	No	1.00				
	Yes	***0.50***	***-0.69***	***0.000***	***0.41***	***0.62***
	Missing	***0.35***	***-1.04***	***0.000***	***0.25***	***0.50***

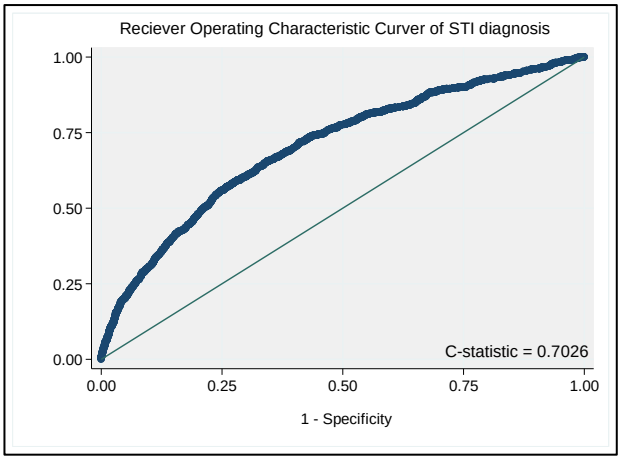
Behavioural risks included: prior chlamydia diagnosis (OR: 3.66, 9% CI: 2.88, 4.65), multiple partners in the prior 3-months; and having a new partner. Condom use at last sex was protective (OR: 0.50, 95% CI: 0.41, 0.62).

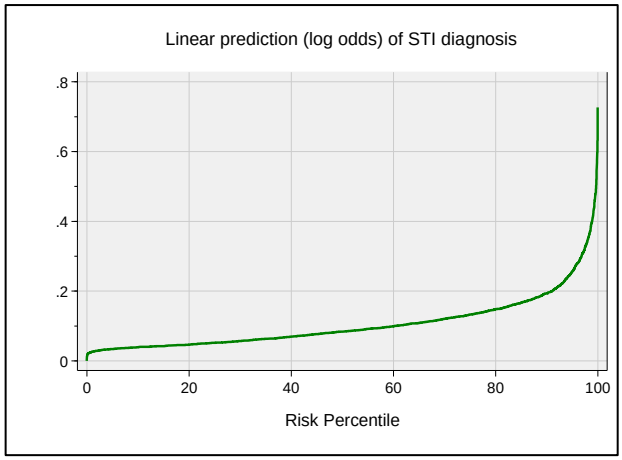
The model had reasonable performance, with a pseudo R^2 of 7.8% and c-statistic of 0.703. The Hosmer-Lemeshow test showed good model fit (p-value = 0.1602). The models predicted probabilities range from 1 – 75%, with a mean of 12%. Using a risk cut-off of 15%, you would refer 19% of patients, with a sensitivity of 42% and specificity of 84% (**Table 9, Figure 3**).

Table 9: Sensitivity, specificity, PPV and NPV values for different risk prediction thresholds in the young person's model

Prediction threshold	**STI (n=1005)**	**No STI (N=8525)**	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Correctly classified**	**% referred**
>5%	905	6411	90.0%	24.8%	12.4%	95.5%	31.7%	76.8%
>10%	673	3118	67.0%	63.4%	17.8%	94.2%	63.8%	39.8%
>12%	581	2304	57.8%	73.0%	20.1%	93.6%	71.4%	30.3%
>15%	**425**	**1385**	**42.3%**	**83.8%**	**23.5%**	**92.5%**	**79.4%**	**19.0%**
>18%	309	861	30.8%	89.9%	26.4%	91.7%	83.7%	12.3%
>20%	252	605	25.1%	92.9%	29.4%	91.3%	85.8%	9.0%
>30%	112	192	11.1%	97.8%	36.8%	90.3%	88.6%	3.2%

Figure 3: Model performance graphs for the primary Young Persons model





Sensitivity analyses

A model fitted using a forward stepwise approach, using a p-value threshold of 0.2, did not exclude any of the variables and therefore had the same model performance.

A model was fitted using multiple imputation. The following variables underwent 10 imputation rounds using chained equations: continent of birth, ethnicity deprivation, and number of partners, new partners and condom use. The model had a pseudo R^2 of 6.6% and c-statistic of 0.688; the predicted risks ranged from 1 – 68%. Overall this showed worse discrimination than the model which included categorised missing values.

A model including demographic data only, and fitted using the v2 dataset (1,045,373 observations), showed considerably poorer model performance, with a pseudo R^2 of 1.4% and c-statistic of 0.590. The range of predicted risk of STI diagnosis was limited, ranging from 2 – 24%, reflecting poor discrimination. A typical high risk individual based on demographics alone would be an 18-19 year old, Black Caribbean male, born in Europe and living in an area of high deprivation (predicted risk – 23%).

3.4.3 MSM Model

Variable Selection

Similarly to the young person's model, age and deprivation were included as categorical variables and ethnicity and country of birth were reduced to fewer categories due to the lack of heterogeneity within the sample. Within this cohort of MSM, there was a range of prior STI diagnoses reported, including HIV, syphilis, chlamydia and gonorrhoea. Many of these contained too few records to be included as individual predictors; therefore a single binary variable indicating STI in the prior 12-months was used. Problematic alcohol use excluded for having too much missing data.

Table 10 summarises the variables in all the models from this point forward.

Table 10: Variables and their definitions in the primary MSM model

Demographic	
Ethnicity	White (reference), White other, S. Asian, Asian other, Black Caribbean, Black other, White and black mixed, mixed other, Other, Missing
Continent of birth	UK (reference), Europe, Africa, Americas, Asia, Other, Missing
STI diagnosis	No (reference), Yes – within the last year
Age	<20 (reference), 20-24, 25-34, 35-44, 45-64, >=65 years
Deprivation score	Quintiles – least deprived (reference)
Behavioural	
Number of partners	None (reference), One, Two – Four, Five or more, Missing
Condomless anal sex	No (reference), Yes, Missing
Known HIV positive partner	No (reference), Yes, Missing
Any drug use in the prior 3-months	No (reference), Yes, Missing

Primary Analysis

The model was fitted, using categorised missing values, with 36 degrees of freedom, and may therefore be over fitted (**Table 11**). In the MSM model, the only significant demographic predictors of STI diagnosis were being of South Asian ethnicity (OR: 2.53, 95% CI: 1.05, 6.10), or being born in Europe (OR: 2.46, 95% CI: 1.26, 4.78). Significant behavioural risks included having had condomless anal sex in the previous 3 months (OR: 1.95, 9% CI: 1.39, 2.73), and any drug use prior 3 months (OR: 1.89, 95% CI: 1.31, 2.74).

The model had reasonable performance, with a pseudo R^2 of 7.0% and c-statistic of 0.676. The Hosmer-Lemeshow test showed good model fit (p-value = 0.224). The models predicted probabilities range from 3 – 71%, with a mean of 16%. Using a risk score threshold of 30% would result in 1 in 5 patients being classified as high risk of STI diagnosis, with a sensitivity of 38.7% and specificity of 84.8% (**Table 12, Figure 4**).

Table 11: Full multivariable logistic regression model for STI diagnosis in the current visit in MSM

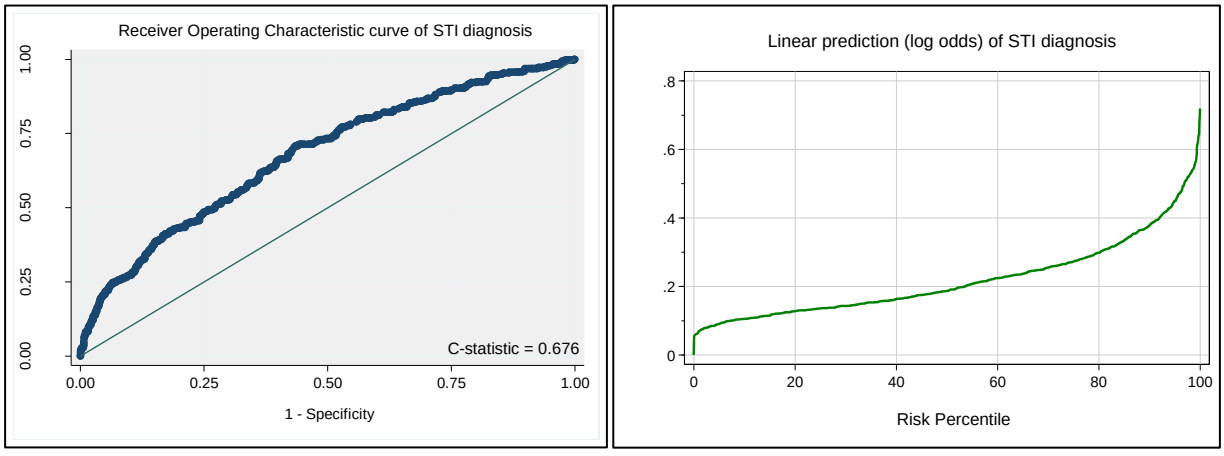
Variable		Odds ratio	Coefficient	p-value	95% confidence interval	
Ethnicity	White British	1.00				
	White, other	0.67	-0.40	0.236	0.35	1.30
	South Asian	***2.53***	***0.93***	***0.039***	***1.05***	***6.10***
	Asian, other	1.43	0.36	0.518	0.48	4.21
	Black Caribbean	0.57	-0.56	0.307	0.20	1.67
	Black, other	0.98	-0.02	0.957	0.47	2.03
	White & black mixed	0.76	-0.28	0.569	0.29	1.97
	Mixed, other	1.19	0.17	0.676	0.53	2.70
	Other	1.05	0.04	0.947	0.28	3.90
	Missing	1.99	0.69	0.159	0.76	5.20
Continent of birth	UK	1.00				
	Europe	***2.46***	***0.90***	***0.008***	***1.26***	***4.78***
	Africa	1.00	0.002	0.995	0.42	2.42
	Americas	1.43	0.36	0.417	0.60	3.40
	Asia	1.23	0.21	0.737	0.37	4.16
	Other	0.88	-0.13	0.796	0.33	2.32
	Missing	0.65	-0.43	0.185	0.35	1.23
Age	<20 years	1.00				
	20-24 years	0.75	-0.28	0.364	0.41	1.39
	25-34 years	0.79	-0.24	0.409	0.44	1.39
	35-44 years	0.63	-0.47	0.141	0.34	1.17
	45-64 years	0.55	-0.59	0.076	0.29	1.06
	>=65 years	0.41	-0.89	0.117	0.13	1.25
Deprivation	Quintile 1 (highest)	1.00				
	Quintile 2 (high)	0.93	-0.07	0.708	0.63	1.36
	Quintile 3 (medium)	0.87	-0.14	0.504	0.57	1.32
	Quintile 4 (low)	1.08	0.08	0.716	0.72	1.63
	Quintile 5 (lowest)	0.66	-0.41	0.094	0.41	1.07
	Missing	1.15	0.14	0.709	0.56	2.35
Previous STI	No	1.00				
	Yes	1.40	0.33	0.150	0.89	2.20
Number of partners	0 partners	1.00				
	1 partner	1.24	0.21	0.604	0.55	2.76
	2-4 partners	1.30	0.26	0.524	0.58	2.93
	>= 5 partners	1.70	0.53	0.219	0.73	3.97

	Missing	1.01	0.01	0.976	0.44	2.36
Unprotected anal intercourse	No	1.00				
	Yes	***1.95***	***0.67***	***0.000***	***1.39***	***2.73***
	Missing	0.89	-0.12	0.758	0.43	1.86
Known HIV positive partner	No	1.00				
	Yes	1.52	0.42	0.065	0.98	2.37
	Missing	1.15	0.14	0.681	0.59	2.22
Drug use in prior 3-months	No	1.00				
	Yes	***1.89***	***0.64***	***0.001***	***1.31***	***2.74***
	Missing	1.29	0.25	0.210	0.87	1.91

Table 12: Sensitivity, specificity, PPV and NPV values for different risk prediction thresholds in the MSM model

Prediction threshold	STI	No STI	Sensitivity	Specificity	PPV	NPV	Correctly classified	% referred
>10%	308	1018	96.9%	9.9%	23.2%	91.8%	29.0%	91.6%
>15%	262	714	82.4%	36.8%	26.8%	88.1%	46.8%	67.4%
>18%	227	531	71.4%	53.0%	30.0%	86.8%	57.0%	52.3%
>20%	209	452	65.7%	60.0%	31.6%	86.2%	61.3%	45.6%
>25%	157	294	49.4%	74.0%	34.8%	83.9%	68.6%	31.1%
>30%	123	172	38.7%	84.8%	41.7%	83.1%	74.7%	20.4%
>35%	86	111	27.0%	90.2%	43.7%	81.5%	76.3%	13.6%

Figure 4: Model performance graphs for the primary MSM model



Box 3: Worked example of the triage tool

The model regression equation is used to calculate the patient log odds, using the following equations:

Patient's log odds of STI diagnosis = constant + (var_1 x $coefficient_1$) + … + (var_i x $coefficient_i$)

Patient's Odds of STI diagnosis = $e^{(patient's\ log\ odds\ value)}$

Probability of STI diagnosis = [Odds / (1 + Odds)] x 100

Taking the young person models:

Log odds of STI diagnosis = -2.34 + (south Asian x -0.32) + (other Asian x -0.06) + (black Caribbean x 0.98) + (other black x 0.45) + (other white x 0.28) + (mixed white & black x 0.61) + (mixed other x -0.13) + (other ethnicity x -0.37) + (missing ethnicity x -0.16) + (born Africa x -0.42) + (born Asia x -0.86) + (born Europe x 0.03) + (born Americas x -0.26)+ (born other x -0.12) + (born missing x -0.24) + (age 18-19yrs x -0.26) + (age 20-21yrs x -0.21) + (age 22-23yrs x -0.36) + (age 24-25yrs x -0.48) + (deprivation 2nd x -0.10) + (deprivation 3rd x -0.004) + (deprivation 4th x -0.18) + (deprivation 5th x -0.22) + (missing deprivation x 0.13) + (prior chlamydia x 1.30) + (1 partners x 0.77) + (2-4 partners x 0.92) + (>= 5 partners x 0.95) + (missing partners x 0.40) + (new partner x 0.37) + (new partner missing x 0.64) + (condom use x -0.69) + (missing condom use x -1.04)

Taking the example of a black Caribbean, 19 year female, who lives in an area in the second quintile of deprivation. She was diagnosed with chlamydia in the previous 12 months, has had 2 partners in the previous 3-months, of which one was new. She used a condom at last sex. In this case, the regression equation for this patient would look like:

Log odds of STI diagnosis = -2.34 + (black Caribbean x 0.98) + (born UK x 0) + (age 18-19yrs x -0.26) + (deprivation 2nd x -0.10) + (prior chlamydia x 1.30) + (2-4 partners x 0.92) + (new partner x 0.37) + (condom use x 0)

Log odds of STI diagnosis = *0.87*

Patient's Odds of STI diagnosis = $e^{(0.87)}$

Patient's Odds of STI diagnosis = 2.39

Probability of STI diagnosis = [2.39 / (3.39)] x 100

Probability of STI diagnosis = 70.5%

This is therefore an example of a very high risk patient, with the model predicting a 70.5% likelihood of them being diagnosed with an STI.

Sensitivity Analyses

Using a forward stepwise approach to the model, with a p-value threshold of 0.2, excluded age, deprivation quintile, number of partners and ethnicity. This model was favoured according to the BIC statistic, but had a poorer discrimination (c-statistic = 0.658) and model fit (pseudo R2 = 5.8%); BIC tends to favour parsimonious models which include fewer explanatory variables.

A model was fitted using multiple imputation, which underwent 10 imputation rounds using chained equations of continent of birth, ethnicity, deprivation, and number of partners, sex with a known HIV positive partner, condomless anal sex and drug use in the prior 3 months. The model had a pseudo R^2 of 6.8% and c-statistic of 0.676; the predicted risks ranged from 4 - 71%. This model showed very similar performance and discrimination to the mode which included categorised missing data, and similar direction and magnitude of relationships with the outcome.

A model including demographic data only with the v2 dataset (245,863 observations), showed very poor model performance, with a pseudo R^2 of 0.5% and c-statistic of 0.553. The range of predicted risk of STI diagnosis was limited, ranging from 7 – 23%, reflecting poor discrimination. A typical low risk individual based on demographics alone would be a >65-year-old South Asian living in an area of low deprivation, who was born in Asia (predicted risk: 7%). This is contradictory to the v3p2 model, in which being South Asian was one of the main risks for STI diagnosis.

3.5 Discussion

We developed two triage tools, for young people and MSM groups, based on routinely collected demographic and limited behavioural data as part of a pilot implementation of GUMCADv3. Overall, both models showed borderline reasonable, but not good, performance with the young person's model (c-statistic = 0.706) having slightly improved performance than the MSM model (c-statistic = 0.676). A c-statistic of >0.7 is generally considered the threshold for a diagnostic to be clinically reasonable. The inclusion of STI history and behavioural data was crucial to model performance, with models based on demographic showing very poor performance (c-statistic = 0.590 and 0.553 for young people and MSM respectively).

3.5.1 Young People

The young person's model identified several significant predictors of STI diagnosis, as well as protective factors, such as being female, being older than 17 years and reporting condom use at last

sex. This agrees with previously published literature which has also found older age and condom use to be associated with lower risk of STI diagnosis in other settings.[107-109] Similarly, multiple partners and prior diagnoses are established risks for STIs amongst young people.[15, 108, 110] The finding that young people of black ethnicities (Including Black Caribbean) and mixed white and black ethnicity are at higher risk of STI diagnosis agrees with previous findings from the UK.[111, 112] Amongst young people, possible explanations for this association may be around different levels of sexual health knowledge, and therefore behaviours, amongst younger and black ethnic minorities.[113]

Applying the young person's model as a triage tool within a clinical setting requires a threshold to be set, with patients having a score above the threshold categorised as 'high risk of STI diagnosis' and those below the threshold as 'low risk of STI diagnosis'. The risk predictiveness curve (**Figure 3**) shows that most young people were relatively low risk, with predicted risk rising sharply from 20 – 75% in only 10% of the population. Using a predicted risk threshold of >20%, where the slope of the curve rises steeply, results in a sensitivity of 25% and specificity of 93%. Applying a lower threshold of >15% improves the sensitivity to 42% and reduced the specificity to 84%; however this would double the number of patients classified as 'high risk of STI diagnosis' (9% versus 19%). While this lower threshold increases sensitivity, the feasibility of delivering a brief intervention to one in five young people may not be possible.

3.5.2 MSM

The MSM model only identified four significant predictors of STI diagnosis: being of South Asian ethnicity (OR: 2.53), being born in mainland Europe (OR: 2.46), having had condomless anal sex in the previous 3-months (OR: 1.95) and drug use in the prior 3-months (OR: 1.89). The use of drugs has been reported as a risk for STI diagnosis by multiple studies, so this finding would be expected.[16, 20, 114] However, the lack of association seen between number of partners and STI diagnosis contradicts multiple studies which have found it to be a significant risk, as we found in young people.[16, 17, 115] In fact, when we used a forward stepwise modelling approach, number of partners was not retained in the model, along with age, deprivation and ethnicity. Compared to other reports of risks for different STIs in the UK, the finding that being of South Asian ethnicity is a significant risk was unexpected;[116] this may be the result of small numbers of observations (n=33), a handful of cases in this group could result in a significant relationship.

The risk predictiveness curve for the MSM model (**Figure 4**) showed a more consistent increase in risk of STI diagnosis across the population, suggesting that more patients are higher risk amongst MSM than young people where it is concentrated in a small proportion of the population. Amongst MSM,

half the patients have a predicted risk of an STI >20%, which explains the models poorer ability to discriminate than the young person's model. Using a predicted risk threshold of >30% would result in 20% of the MSM clinic population being classified as 'high risk of STI diagnosis', with a sensitivity of 39% and specificity of 89%. A threshold of >20% would give a better balance of sensitivity and specificity (66% and 60%, respectively), but results in 46% of patients being 'high risk of STI diagnosis'.

3.5.3 Implementation challenges

A key challenge of implementing risk scores for triaging in real-world clinical settings is the need to balance sensitivity and specificity, and available resources. The aim of this pilot study was to demonstrate feasibility of triaging patients into different behavioural risk reduction interventions, crucially, within existing clinical resources. Therefore, the decision about what threshold to use when operationalising the triage is likely to be driven more by the proportion of patients classified as high risk, rather than optimising either the sensitivity (identifying more true positives) or specificity (identifying fewer false positives). Based on this being the priority, a risk threshold of 20% for young people and 30% for MSM may be the best balance between resources, sensitivity and specificity.

A potential challenge for this approach, assuming high risk patients would all be referred to an intervention which requires a level of clinic resources, would arise if clinic populations differ dramatically in terms of their demographics and sexual behaviours. A clinic which see mostly lower risk patients, for example young people who are mostly female of white or Asian ethnicity and aged >18 years, would likely classify less than the expected 9% high risk patients. In comparison, a clinic with more young black men attending would likely classify more than 9% as high risk, resulting in an unequal burden on resources.

3.5.4 Strengths and limitations

In general, the young people and MSM populations were representative of the wider clinic populations from the five pilot sites in terms of continent of birth, deprivation and ethnicity. MSM patients tended to have lower levels of missing data than young people and general populations; therefore it is likely that the two populations used in the model development reflect the wider population of these clinics. However, these clinics may not be representative of national GUM clinic attendance. For MSM specifically, the STI rate in this sub-sample was higher than the nationally reported rate for the same time period (22% versus 15%), but conversely does not include any of the higher risk London clinics with large MSM populations.[18] The pilot clinics were all located in the south

of England, and therefore the demographic profile of patients within models are unlikely to be generalizable nationally.

A limitation of the v3p2 dataset is the level of missing data within the behavioural variables. While the behavioural variables are recommended as part of the BASHH guidelines and are intended to be feasible for collection in routine care,[96] in practice this may not be the case. As the level of missing data differs between young people and MSM, it suggests that these questions were not asked to patients randomly, but rather that clinical staff selected who they asked and recorded data for based on personal characteristics. For example, a young woman attending a GUM clinic for contraception may be less likely to have their recent sexual behaviour recorded than those attending for an STI screen. We found that MSM were much more likely to have (49% vs. 31%) drug use recorded than the general population, potentially reflecting awareness of chemsex being more common risk behaviour in MSM. As it is reasonable to assume the missingness is not random and there are several mechanisms which could lead to this missingness, our primary models would not have accounted for this. Improving data completeness for the limited behavioural data, across the whole clinic population, would likely improve model performance and discrimination. This would also allow for additional variables to be included in the triage tool, such as problematic alcohol use.

We did not conduct any internal validation of either model, therefore we cannot comment of how well the model would generalise to a different dataset. The young person's model met the rule of thumb to prevent over-fitting that there should be 10 outcome events per degree of freedom in the model, with 1005 outcomes and 34 degrees of freedom. The MSM model however was fit with 36 degrees of freedom for 318 outcomes; therefore it is likely to be over-fitted, despite having poorer performance. External validation was planned during the pilot feasibility trial implementation, providing a more robust method of model validation than internal validation.[106]

3.6 Conclusion

Triaging patients into high or low risk groups, based on routinely collected data within sexual health clinics showed reasonable discriminatory ability; however at a minimum, basic behavioural data is needed to improve the discrimination of these models. The ability to include additional, or more complete, behavioural data would likely improve performance further. The models were developed using the only dataset available at this time, from a pilot that included a small sample of clinics, which were not representative all of all clinics in the UK (e.g. larger London clinics with a high proportion of high-risk patients were not able to be included). While the work demonstrated that developing such a

tool was possible to a minimal threshold of clinical utility, further refinement and external validation is needed to improve the performance of the tool and assess the real-world applicability of this approach.

Chapter 4: Work Package 3 – Current opportunities, barriers, and preferences for behavioural interventions

4.1 Background

Attendance at a sexual health clinic provides an opportunity to deliver interventions at a potentially 'teachable moment'. In-line with this, NICE recommends that high risk groups, including young people and MSM, should undergo risk assessment at sexual health services. Those considered at high risk are recommended to receive a brief structured one-to-one risk reduction intervention.[117] There is currently a lack of evidence from the UK as to how patients are being triaged in clinics, what criteria are being used to determine risk, and what interventions are being offered. Considering the range of potential evidence-based interventions identified in WP1,[47] understanding what is currently offered as standard of care across diverse services is important.

Taking account of the views of stake holders, including service users and staff who deliver interventions is vital to the design and implementation of interventions that are acceptable, practically feasible and sustainable over time.[34] Co-creation of interventions with stakeholders is important to the Intervention Mapping (IM) approach to intervention development and adaptation.[118] This iterative process combines an ecological approach with participation of all stakeholders, a focus on specification of the underlying mechanisms (in a clear logic model) and a research-based approach to ensuring fidelity of implementation. A key part of this process is to refine modes of delivery and delivery competencies that maximise intervention effectiveness in real-world contexts.[119] Understanding service user and provider preferences for different intervention approaches, and the motivation for these preferences forms part of the IM process. This part of the project therefore used qualitative and quantitative methods to obtain evidence to inform the IM process.

4.2 Aim

To describe current practice in sexual health clinics with respect to triage and delivery of sexual risk reduction interventions, and to explore opportunities and challenges to the delivery of candidate risk reduction interventions.

4.3 Method

We conducted a mixed-methods study with healthcare providers and service users, using four phases of data collection.

4.3.1 Key informant provider interviews

Key informant interviews were conducted with a range of service providers to explore the current use of triage methods and behavioural interventions in SH services in England. We explored respondents' views on the opportunities and challenges to the delivery of sexual risk reduction interventions within existing resources in SH services.

Participant selection*:* We purposively recruited a range of health care providers, to include: service leads, health advisors, doctors and nurses. Providers were targeted to reflect different types of clinics, sizes, geographic locations and client mixes. Selection of clinics was done through individual contacts and through random selection from the list of clinics provided by PHE, which was done in Stata. In total, we aimed to conduct 30 interviews.

Recruitment: Interviews were pre-booked, following an invitation sent by email. Participants were contacted up to three times by email, before they were considered as not interested in taking part.

Data collection: The interviews were conducted by telephone. Interviews lasted approximately 30 minutes in total, and consent was taken verbally at the start. The interviews were audio-recorded and transcribed by a professional service.

Analysis: Analysis used the framework approach, a deductive approach, which allows for a more structured approach to data analysis based on pre-determined aims and objectives as well as accommodating emerging themes. Content analysis was conducted independently by two researchers and themes were agreed through discussion until consensus was reached. Both pre-determined concepts used for developing the topic guides and emergent themes arising from the data informed the process of identifying the key thematic categories to be used in data coding.[120, 121]

4.3.2 Web-based service provider survey

A brief web-survey was conducted with sexual health service providers to determine current triage and intervention strategies in use across England, and the resources that are available for these. The content of the web-survey was informed by findings from the analysis of the key informant provider interviews, and therefore the survey was conducted sequentially to the interviews.

Study population: All sexual health services that report to the PHE GUMCADv2 reporting system were eligible to participate. This includes level-1, 2, and 3 services within England. An estimated 570 services were reporting to PHE at the time of the survey, and a list of clinic contacts was provided by PHE. A supplementary list of clinic contacts was provided by Tom Nadarzynski (BSMS, PhD student), and used to update contact information.

Data collection: Providers were contacted by email, which contained study information and the link to the web-survey. Up to five email reminders were sent, over a 6-month period (December 2015 – June 2016), with three generic and two personalised emails sent. The link to the survey was also distributed in the delegate packs at the British Association for Sexual Health and HIV (BASHH) 2016 annual conference. The survey was developed in Opinio which is hosted within UCL servers, and was designed to take 10 minutes. The survey was piloted by two independent clinicians who work in level-3 services to check for understanding and language. No personally identifiable information was collected.

Analysis: The survey was analysed using descriptive statistics, adjusted for clinic type, and location. All analysis was done using Stata 13.

4.3.3 Semi-structured interviews with patients

Interviews with service users were conducted to gain an understanding of patient perceptions of risk and their attitudes towards different risk reduction interventions, to inform acceptable and desirable interventions.

Participant selection: We purposively sampled young men and women, and MSM who were attending NHS sexual health services. The recruitment framework categorised MSM by age and young people by age and gender, with equal recruitment across two clinic sites. A total sample of 15 heterosexual young people and 20 MSM were targeted (total = 35).

Recruitment: Participants were recruited from two sexual health clinics: Claude Nicol, Brighton and Mortimer Market Centre, London. Participants were approached in the clinic waiting room and given a study information sheet to read before deciding to take part. Participants were offered a £20 high-street voucher as a thank you for taking part. Interviews were either scheduled to take place on the day of recruitment, or scheduled for a future time.

Data collection: Interviews were conducted by researchers in person within the clinical setting. Interviews were designed to last 30 minutes, and were piloted with members of the PPI group to check for understanding and sensitivity. Written consent was taken prior to the interview starting, and the interviews were audio-recorded and then transcribed using a professional service.

Analysis: We used the same analysis methodology as described for the healthcare provider interviews.

4.3.4 Patient discrete choice experiment

We conducted a cross-sectional discrete choice experiment (DCE), to assess patient preferences for risk reduction interventions. DCEs are based on the premise that services can be described in terms of their 'attributes' and 'levels' (or characteristics) and that an individual's preference, and therefore choice, of service is based on a combination of these characteristics. Information from WP1 and both provider and patient interviews were used to define the key issues of importance (attributes and attribute levels) that may influence patients' preference.

Study population and sample size: We recruited young people and MSM who were attending a NHS sexual health clinic, aiming for a representative sample of attenders within these groups. DCEs are not amenable to conventional power calculations in advance of developing the instrument. However, other studies using DCE methods to assess preferences for healthcare have typically included 200 participants.[122] As we planned sub-analyses in young people and MSM, we aimed to recruit 350 participants.

Recruitment: Patients were recruited from three sexual health clinics: Claude Nicol, Brighton; Mortimer Market Centre (MMC), and Archway, London. Participants were approached in the clinic waiting room and given a study information sheet to read before deciding to take part.

Instrument design: The questionnaire used a 'labelled' rather than generic design. Four modes of brief behavioural intervention were included in the final design: 'talking' to someone (meaning talking therapies such as counselling and motivational interviewing), an 'email or text containing

health advice', an 'online session by yourself' or an 'online group session' plus a fifth 'opt out option' (Error! Reference source not found.**13**). The attributes included: type of contact, type of activity involved in each session, length and number of sessions, and the person who mediates the sessions. Note however that each attribute was not necessarily applicable to each intervention, e.g. a person is not needed to mediate an email / text based intervention. The number of sessions (1 to 6) and their length (15 minutes to an hour) were deliberately short to reflect the brief nature of the interventions shortlisted.

Table 13: DCE attributes and levels

Attribute	**Options**				
	Email or text containing health advice	**Online session by yourself**	**Online group session**	**Talking with at least one person**	**Opt out**
Type of contact	Emails or texts from a NHS service containing health information	Interactive online information including videos and quizzes	A Facebook Group Chat or Twitter (or similar online social media)	1:1 phone conversation, 1:1 face-to-face meeting in clinic, group face-to-face meeting in clinic	N/a
Type of session	Reading emails / texts	Typing questions and responses	Read / watch online and ticking boxes via a webpage or app	Talking	N/a
Length of each session	N/a	Up to 15, 30 or 60 mins	Up to 15, 30 or 60 mins	Up to 15, 30 or 60 mins	N/a
Number of sessions	N/a	1, 2-3 or 4-6	1, 2-3 or 4-6	1, 2-3 or 4-6	N/a
Person who mediates the session	N/a	N/a	A health counsellor, nurse or peer	A health counsellor, nurse or peer	N/a

The pilot questionnaire was generated using an orthogonal approach and set to 12 choice tasks given 12 degrees of freedom in the design using the Ngene V1 software (http://www.choice-metrics.com/). It was completed by 24 clinic attendees. The pilot design required participants to

make two choices per DCE question. The first included an 'opt out' option; this was omitted in the second (referred to as a 'forced choice' question). This two stage approach was included to evaluate concerns that a large number of participants would 'opt out'. However, the forced choice question was removed from the final design, as only a minority of responses indicated a preference not to participate. The final instrument was produced using a d-efficient approach using priors from the pilot. Participants were asked to complete all 12 DCE questions. Eight versions of the questionnaire were produced in which the ordering of the DCE options and questions were changed.

Data collection: The paper questionnaire was given to patients once they signed a consent form, and asked to complete it while in the waiting room. The questionnaire was designed to take 10 minutes. Participants were asked to provide limited demographic and risk behaviour information, including: age, gender, ethnicity and sexual orientation. The questionnaire was piloted with patients in one clinic to check for understanding. Data was entered into an Access database.

Data analysis: Analysis used conditional logistic (CLOGIT) and latent class models (LCMs). CLOGIT models were the basic form of analysis but since the results are presented for the 'average' respondent, they do not address issues of heterogeneity. LCMs address heterogeneity by assuming the population of interest consists of a number of pre-specified latent classes with a probability each individual belongs to each class. Likely 'membership' of each class is estimated as a function of pre-specified covariates: born in the UK (yes / no), having tested for a STI within the past year (yes / no), previously diagnosed STI (yes / no), and risk group (heterosexual 16-20 yrs, heterosexual 16-25, MSM 16-25, MSM 26-50 and MSM 51+). The number of classes was determined by selecting the number of classes in the model with the lowest BIC and examination of the standard errors on the coefficients.

All results are presented as odds ratios and 95% confidence intervals (CI's) based on robust standard errors given each participant provided multiple responses. All attribute levels were dummy-coded (1 for group membership, 0 otherwise) except when estimating the alternative specific constants (ASCs). The ASCs represent the extent to which people preferred one of the intervention options or opting out when all other factors are disregarded. That is, they indicate the strength of preference for each individual label. For the ASCs, effects coding was used (1 for group membership, -1 otherwise) to avoid confounding with the base levels on the main attributes. 'Email or texts' was used as the reference option in all analyses. Statistical analyses were performed using Stata 14 and NLOGIT 5, the scenario evaluation was undertaken using Excel.

4.4 Results

4.4.1 Key informant provider interviews

A total of 40 healthcare providers were individually contacted by email, and 26 telephone interviews were subsequently completed. Those interviewed included a mix of clinical leads, nurse practitioners and health advisors, from level 2 and 3 services inside and outside of London (**Table 14**).

Table 14: Healthcare provider participants in key-informant interviews

	Number	Job title	Location
Level-2	8	Nurse = 5 Doctor = 3	London = 3 Non-London = 5
Level-3	18	Health advisor = 7 Nurse = 1 Doctor = 10	London = 9 Non-London = 9

<u>Current Services</u>

Most staff reported a mixture of appointment and walk-in services, with variety between clinics on how patient pathways are set up. Level-2 services, many of which are nurse-led, have set clinic times for specific procedures (e.g. coil fitting) which ca require involvement of different specialities and are therefore appointment based. Self-check-in and booking was mentioned by two GUM clinics: "*Before they see the doctor or the nurse, there will be a, sort of, kiosk that will ask them pertinent questions in a way just to save time. So the majority of the history taking, if you like, will be done on the, sort of, electronically by patients*" (Doctor, level-3).

Several clinic staff reported having specific services and pathways for young people and MSM groups. The age cut-off for 'young' varied from 16 to 19 years and under, and the change in the pathways included additional questions, assessments for vulnerability and speaking to a health advisor. "A*n MSM who's in his 20s or 30s, whatever, with symptomatic, so we have a policy of do-not-turn-away, we need to see that person and treat them"* (Nurse, level-3). Other services were offered by participating clinics, with little standardisation in how the services were set-up; these included: contraceptive clinics, drug and alcohol services, psychological services and condition specific (e.g. warts) services. Referrals to external services also varied between clinics, including:

GUM services (by level-2 clinics), sexual assault or domestic abuse, drug and alcohol services, charities (such as London Friend or THT) and other clinical specialties (e.g. psycho-sexual).

A variety of triage methods and their purposes were described by staff from different clinics. Examples of how triage rules varied included: "*MSM with greater than X number of partners*" (Doctor, level-3) or "*Somebody who is displaying a sexual behaviour where there is multiple partner change*" (Doctor, level-3). Not all clinics had set rules, with triage lacking standardisation. "*Well we have guidelines. We have sort of GUM guidelines, departmental guidelines, but it's down to the individual doctor or nurse, seeing the patient, to decide whether someone should see the health adviser*" (Doctor, level-3). One participant reported having an electronic triaging system, similar to the proposed approach in this project. "*The system, the way it's devised, does flag up to say this patient needs to see a health advisor because of risk A and B and it lists it down for you, what the clinician in the room has ticked*" (HA, level-3).

Clinic staff reported offering a range of sexual health promotion and risk reduction interventions, some more formally than others. Many of these activities were not specifically funded, but were done within existing resources: "*So we just get paid as a level two sexual health screen regardless of whether we offer an intervention or not*" (Nurse, level-2). Informal interventions included condom distribution and general health promotion messages, which were reported as being done by all clinic staff: "*I mean, I think, really, sexual health promotion is just sort of integral to every kind of consultations so, in a way, some degree of sexual health promotion should be happening in every consultation*" (Doctor, level-3). Various national campaigns were being delivered by clinics, such as the C-card initiative [123], and the Sex Positive campaign by Brook [124]. More formal risk reduction interventions focussed on one-to-one sessions and outreach or educational services. One-to-one sessions in level-3 services were generally performed by HAs or counsellors, rather than all clinical staff: "*So to a certain extent, the majority of staff have had some training in motivational interviewing […] if someone starts to need more intensive motivational interviewing interventions, they're referred to the health advisors*" (Doctor, level-3). The one-to-one intervention method mentioned most often was motivational interviewing. Brook specifically reported a longer 6-week educational programme about self-esteem and sexual health.

<u>Proposed Triage</u>

The proposed Santé approach was generally seen as something which was done already and this resulted in some respondents not being sure of the utility: "*we already have, well, it's not a tool, but we have a means to ask people, so if anything was going to be developed that had a chance of being used it would have not to increase the length of time*" (Doctor, level-3). However, this led others to

state it could be acceptable: "*I think that would work because we do triage forms which give us a little bit of a clue*" (HA, level-3). Potential barriers to the proposed triage included: increasing the time needed with patients, how well the score would perform, training required in using it, how the patient referral would work, and issues in adapting EPR systems. On the other hand there were several opportunities highlighted, such as the perceived benefits of standardisation and accurate prediction, ease of having an EPR-based system, and potential patient acceptability.

Proposed Interventions

We presented the following intervention types to the HCPs, and asked for both the opportunities and barriers to potentially implementing them in their setting: videos in the waiting room, group sessions, online resources including mobile phone 'apps', single and multiple one-to-one sessions.

HCPs gave mixed opinions on videos, with the practical ease of implementing them and having a potentially receptive and captive audience given as opportunities: *"It's an easy way for people to kind of… people aren't doing very much, so it's quite a good time to kind of drill it in"* (HA, Level 3). However, there were concerns with the lack of targeting and appropriateness for diverse waiting rooms: *"we have a very heterogeneous waiting room for the walk-in clinic, you know. The challenge, I guess, would be how you target that, or do you have a number of different ones for different risk groups"* (Doctor, Level 3).

Patient group sessions as an intervention format was, on the whole, not well received (e.g. *"I think that's a non-starter"* – HA, level-3). The barriers to using group sessions focussed on resource issues, with a lack of appropriately trained staff, staff time, lack of clinic space and general disruption to the clinic running smoothly. HCPs also anticipated low patient acceptance: *"personally, if I was a patient, I'd run out screaming if somebody tried to get me to do some group-work when I'm sitting in a clinic that I might feel slightly uncomfortable about, anyway"* (Nurse, Level 3). Positive aspects to group sessions were highlighted, although were mostly assigned to specific risk groups and support group models. Another was being opportunistic and engaging with patients while they are at the clinic: *"Catch them while they're waiting you know, they haven't got anywhere to go"* (Nurse, level-2). One HCP reported offering a group intervention and another that they had done so in the past.

Some clinic staff reported having online resources and apps which they refer patients to; specific examples included dedicated online education tools for psychosocial issues. There was generally a positive attitude to using digital interventions, across staff and clinic types. The main barriers concerned patient motivation and uptake and a current lack of tools to refer patients to: *"There's so much else to distract them on the internet, but unless it's something they enjoy doing, the learning is*

not going to happen unless it's couched in a very user-friendly, quick, vehicle" (Doctor, Level 3). Opportunities for digital interventions included their accessibility, perceived patient preference and minimal staff delivery time required: *"We have quite an IT-savvy patient group, I would say, so something like that might appeal"* (HA, Level-3) and *"Yeah, well, they love apps. I mean we suggest apps. I'm quite an elderly nurse now but even I know to suggest apps"* (Nurse, Level-2).

Brief one-to-one sessions of MI were mentioned as something offered by all the GUM and the Brook clinics we engaged with. However, it was also an intervention that providers highlighted had a lot of challenges. One participant identified a lack of evidence as a challenge; this was more frequently raised than for other intervention types. The current needs associated with one-to-one sessions focussed on costs and staff resourcing: *"So I think the clinical time, availability of time in the clinic is probably the biggest challenge"* (Doctor, level-3). Patient motivation was also viewed as a barrier, whether the patient would be open to the intervention: *"With behavioural interventions, if people are referring into that service, if you've got to work out whether the patient is really ready for this intervention, because if the patient is not ready for it, it's just no point doing it"* (HA, level-3). The main opportunity that was raised for one-to-one sessions was the flexibility that these offer, and the ability to tailor sessions to individual risks and needs. Many of the HCPs expressed that they felt the brief sessions were effective, even if this is hard to demonstrate: *"Yes I know that's probably not the most cost efficient. But I think that's probably the most effective method of risk reduction, because it is tailored to the actual patient's needs and you have time to explore what their risk is"* (HA, level-3).

Similar opportunities and barriers were raised around a series of one-to-one sessions, with HCPs highlighting the constraints of time and resources available in clinic to deliver these: *"Yes, that's a great idea, but we've never had capacity to do that"* (HA, level-3). There was a perception that this was a good intervention format, and that it could be effective, provided patients were motivated: *"But if it's something that perhaps is reserved for people who are seen as particularly high risk, and particularly amenable to this sort of intervention, then it would have a place"* (Doctor, level-3).

<u>Implementation Challenges</u>:

Financial and staffing constraints were raised frequently as barriers to the delivery of current services, as well as being an anticipated barrier for delivering novel triage pathways or interventions. One approach currently taken to limited budgets was self-sampling: "*All this quick checking and self-assessment has started as a result of changes in funding and competition in sexual health services […] that's where that's all heading*" (HA, level-3). There was a perception that commissioners focused on treatment rather than prevention for STIs and that evidence was needed for a service to be commissioned: "*Commissioners, I think, will not fund anything that hasn't been shown to be*

effective. And so I think you'll have to demonstrate in some way that it is effective and not just that it's acceptable" (Doctor, level-3). Continuity of care was deemed both important and lacking by HCPs, with issues associated with how services are commissioned: "*one of the problems that we face, generally, is that drug and alcohol services generally tend to be borough-based, and all the patients we see come from everywhere*" (Doctor, level-3). Additional services or improvements which were desired by HCPs included outreach for homeless people or sex workers, improved drug services, community education, and PEP follow-up pathways.

4.4.2 Provider web-survey

We received 100 responses, representing 145 clinical services. Of the responses, 82 (82%) were complete. The majority of responses were from Level-3 services (80%), and three were from Level-1 services. Respondents included: clinical leads (41%); doctors (37%); health advisors (8%); and nurses (8%). Respondents had been working within their service on average 10 years (range: 0 – 31 years). The overall response rate was 25%, with a higher response rate among level-3 services (31%).

Current services

Two respondents reported not offering any health promotion or risk reduction intervention services, both of which were level-3 services. **Table 15** describes the services currently being offered by sexual health services in England:

Table 15: Summary of interventions currently delivered by sexual health providers

	Level 3 (n = 80)	**Level 1 and 2 (n = 20)**
Leaflets	65 (81%)	15 (75%)
Educational videos	3 (4%)	1 (5%)
Online learning materials	8 (10%)	5 (25%)
Mobile 'app'	2 (3%)	0 (0%)
Brief 1:1 sessions	56 (70%)	11 (55%)
Multiple sessions of MI	38 (48%)	2 (10%)
Group sessions	7 (9%)	5 (25%)

The least common health promotion activities offered were videos and apps, while leaflets and brief one-to-one sessions were relatively common in both level-2 and 3 services at the time of the survey in 2015/16. Five respondents reported previously showing educational videos; reasons for stopping

included: lack of funding (n=3), no observed impact (n=1) and the materials no longer being available (n=1). Lack of funding was cited as the reason for one clinic ceasing to offer an app, and another for ceasing an online intervention. Clinics which previously offered 'talking interventions' (1:1, multiple sessions of MI and group sessions), HCPs cited a lack of trained staff time as the main reasons for stopping.

Triage

The majority of clinic staff (77%) reported triaging on the basis of sexual health risk; this was less common in level-2 services (68% vs. 84%). No respondents reported the triage decision being an automated (or algorithm-based) decision, with either a nurse, doctor or HA making the decision, along with patient input. Comments in the free text about an automated system were mixed, with many reporting it is "not necessary", while others stated it would be useful, for example: "a good thing as long as not too long and time consuming". Healthcare providers were asked what three factors they considered most important for assessing patient risk of STIs. Sexual orientation, number of recent partners and the types of sexual activity reported (e.g. condomless sex) were the most commonly selected factors, and this was consistent between level-2 and 3 services. These are all variables included in the GUMCADv3 tool.

Overall 14 responses stated that the SH service did not have any EPR system (level-2 = 2 (13%), level-3 = 12 (18%)). Of those with EPR systems, 45 (55%) reported having it amended, of which a quarter stated that it was very difficult to do and 9% were not able to amend their system despite trying.

Intervention barriers and opportunities

Of interventions not currently offered by clinics, the most desired by level-3 services were online learning materials (67%), or mobile apps (64%). Group sessions were the least popular, with only 18% of level 1 and 2 and 23% of level-3 clinics expressing any desire to offer them (**Table 16**).

Table 16: Number of clinics reporting a desire to deliver, or not deliver, different intervention types

	Level 3		**Level 1 and 2**	
	Desired	***Not Desired***	***Desired***	***Not Desired***
Educational videos	30 (46%)	11 (17%)	5 (33%)	3 (20%)

Online learning materials	40 (67%)	6 (10%)	8 (73%)	1 (9%)
Mobile 'app'	41 (64%)	3 (5%)	8 (50%)	0 (0%)
Brief 1:1 sessions	5 (33%)	2 (13%)	3 (60%)	1 (20%)
Multiple sessions of MI	13 (42%)	2 (6%)	3 (21%)	2 (14%)
Group sessions	14 (23%)	29 (48%)	2 (18%)	3 (27%)

*Note: the percentages are calculated based on the number of clinics not already providing this service

For those interventions that clinic staff expressed an interest in delivering, the main barriers and motivations are presented in **Table 17**. Most of the barriers were related to funding and staff time for delivery, while the motivations were around potential effectiveness and uptake (rather than practical reasons). This suggests that if digital or video based interventions were developed for clinics, they would be able (and want) to deliver these.

Table 17: The main barriers and motivations for intervention formats in Level 1, 2 and 3 clinics

Intervention	Barriers	Motivations
Educational videos	Lack of funding for development (37%)	Captive patient audience (37%)
Online learning materials	Lack of funding for development (61%)	Minimal staff time (33%)
Mobile 'app'	Lack of funding for development (65%)	Potential patient uptake (47%)
Brief 1:1 sessions	Time constraints (50%)	Widely appropriate for patients (38%)
Multiple sessions of MI	Lack of funding for staff (50%)	Perceived effectiveness (50%)
Group sessions	Lack of trained staff time (38%)	Encourages peer learning (50%)

*Note: percentages are calculated based on the number of clinics who expressed an interest in delivering this intervention format

Trial feasibility

Respondents were asked if they would be interested in taking part in a cluster Randomised controlled trial (RCT) of brief behavioural interventions, and whether being randomised at the clinic level would be acceptable. Nearly half the clinics (48%) expressed an interest in trial participation, but only 40% reported being comfortable with randomisation. There was no statistical difference between level-2 and level-3 clinics (38% vs 41%, respectively).

4.4.3 Semi-structured interviews with patients

We recruited 35 service users, 15 young heterosexuals and 20 MSM. A description of the participants is presented in **Table 18**.

Table 18: Description of participants in service user semi-structured interviews

	Number	**Gender**	**Age group**	**Ethnicity**
Young people	15	Male = 7 Female = 8	16-20 years = 8 21-25 years = 7	White British =10 White other = 3 Black African = 1 Asian British = 1
MSM	20	n/a	16-25 years = 7 26-50 years = 6 >=51 years = 7	White British = 11 White other = 2 Black British = 2 Black other = 1 Chinese = 1 Missing = 3

The service users we recruited were visiting the clinics for a range of reasons, including routine checks, results and treatment (including as part of partner notification), or because they had symptoms. The reasons were similar between MSM and young people with regular attenders in both groups. Some reported being motivated to attend because they were anxious, especially with symptoms or a recent 'risky' event.

Risk perception

We asked participants about their self-perception of sexual risk, as a way to introduce the concept of our proposed triage approach, and to gain an insight into potential barriers to triage. Trust, or lack of trust of a sexual partner, was frequently associated with service user's perceptions of their sexual risk, driving sexual risk behaviour decisions such as using condoms; this was common between young people and MSM. The concept of causal and regular partners was much more common amongst MSM, and the types of sexual behaviours practiced within these partnerships were different e.g. not using a condom was something only done in a relationship. Young people discussed different levels of trust between people they knew being trusted compared to someone met, for example, via the dating app Tinder.

Use of condoms, a major aspect of risk perception in young people, was reported as being influenced by peers. Young women specifically discussed an inability to negotiate the use of

condoms, or we described by young men as not negotiating condoms: "*it would be a big rarity if a girl basically asked me to put on a condom*" (Male, 21-25 years). There was a perception that peers were not using condoms and that normalized the behaviour; concern about pregnancy was more of a motivation for their use than STI risk. In MSM on the other hand, condom use was seen as a matter of preference. Condom use was also circumstantial, and non-use was often seen as one-off events: "*I like to class myself as someone who is safe with sex but I am not perfect*" (MSM, 16-25 years). Other behaviours which shaped how people felt about their personal risk included drug and alcohol use, general prevalence of STIs in the population and overseas partners.

Risk was seen as dynamic by both groups, and was related to relationship status, age or maturity and either a personal scare or that of someone they know. Commonly being in a relationship was viewed as lower risk and that risk decreased with age: "*I'd like to think that the older people do get the more kind of cautious and aware of STIs they are*" (Female, 16-20 years). More specifically to young people, university was seen as a distinct time where more risks are taken, but that this was self-limited during this period. In MSM, self-esteem was specifically mentioned as affecting risk behaviours: "*if your self-esteem is quite low, its quite possible to engage in un-safer practice than if your self-esteem is quite high*" (MSM, 26-50 years).

Proposed triage

We asked participants about being offered services based on standardised risk assessment, and service users had mixed views. Positive aspects of triaging included the process of having a score acting as an intervention in itself as it may raise awareness about risks that service users had not considered previously: "*it's something that people might not like, but you, kind of have to know, it's better to know*" (Female, 21-25 years). Trust towards the healthcare professional also meant that they would listen as they were seen as knowing best, although this would rely on the triage being well-explained (no 'technical jargon') and trusted: "*you're a registered healthcare professional, so I trust your reasoning*" (Female, 16-20 years). It was acknowledged that while triage might act as a 'shock factor', service users may not be supportive of it at the time but could 'reflect' afterwards. This may not lead to behaviour change however: "*I wouldn't consider changing my behaviour actually, I would just see it as, yes, a warning*" (MSM, 16-25 years).

Concerns raised with triage included anxiety associated with a classification of 'high risk'. Alternatively telling them something they already knew was considered redundant: "*either way I'm going to get tested, so I don't know why they tell people really*" (Female, 21-25 years). Amongst MSM specifically there was concern that it could feel like being pigeonholed simply based on being MSM within a certain demographic: "*with gay culture being so sleazy you just sort of expect to be*

high risk all the time" (MS< 16-25 years). Onward referral based on triage raised concerns that services should be available to everyone, with the denial of services or rigidity of referrals criteria not liked. However, many noted that the offer of supportive services was positive and service streamlining made sense.

Proposed interventions

Similar to the HCP interviews, we asked participants for their thoughts on different intervention formats and any preferences between them: waiting room videos, group sessions, online and apps, one-to-one sessions. Service users raised multiple concerns about videos in the waiting room, suggesting that they would make people feel awkward in mixed waiting rooms or increase their anxiety. One commented, "*having had sex with 20 different people last night, they don't need a video saying don't be promiscuous*" (MSM, 16-25 years). Opportunities however focussed on the notion that education is good, and a sexual health setting is the correct setting for sexual health education: "*Why not?" Information is a good thing. It's a sexual clinic, so that's why people are there, to talk about sex*" (MSM, 26-50 years). Recommendations about content included text information or statistics being desirable and short advert or campaign type clips would be acceptable, but content should not be graphic.

Group sessions were not viewed favourably, with many participants stating they would not take part despite seeing the role they could play. Privacy and confidentiality was the primary concern with this intervention format, as they did not want to talk about sexual health in a group despite considering themselves open: "*you share funny stories with your friends, and I do talk about sex quite a lot with my friends, but not about this part*" (Female, 21-25 years). Amongst MSM this was particularly seen as an issue if someone is shy or isolated: "*they cannot talk at home, they cannot talk at school, and they cannot talk in church and they cannot talk to their own best friends, so they are not going to start talking here*" (MSM, 26-50 years). These concerns were associated with the group or others situations not being appropriate to their circumstances, and that there would be judgement about lifestyle. In MSM, there was also the possibility of bumping into someone known, and HIV status affecting how someone might participate. On the other hand, the ability to learn from others experiences was seen as valuable.

Generally having some form of digitally based intervention (e.g. website, social media or app) was positively viewed, although respondents felt differently about the various formats. While concerns about apps were expressed across participants, this was more distinct in young people; phones were described as shared; with friends and family often looking at them or them being out 'on the table': "*people use my phone, so they would know my business*" (Female, 16-20 years). Apps were

considered somewhat redundant if there was a website available: "*most information I can find it online, I don't need an app just for that […] it's not like you need to check it every day*" (MSM, 16-25 years). In favour of apps however was convenience and immediacy, especially if it could do more than just provide information (e.g. appointments or remote clinical consultation), or gave wider health information. Social media was less popular with concerns over Facebook or Twitter not being anonymous and therefore lacking privacy: "*I wouldn't share my, as much personal information as if I come here and I talk to someone*" (Female, 21-25 years). However, there were some MSM who said they had followed online pages about sexual health, and seen adverts about sexual health promotion advertised through Facebook. More specifically, MSM targeted apps or websites such as Grindr were suggested as good places to have sexual health information. Online formats were viewed as convenient, could be accessed as and when needed, however there was a concern that they needed to be a reliable source to ensure anonymity.

One-to-one 'chatting' interventions were well received and most participants indicated it was their favoured option. Being face-to-face and the element of human interaction was important ("*the thing about, you know, chatting to a human is, they're receptive*", Male, 16-20 years), and the ability to ask questions in a tailored session. The need for the session and what people expected to get out of it was related to their trust in the healthcare provider, both for the referral and what they would share in the session. Negative aspects of this intervention were the possibility of being embarrassed, not seeing it as needed and being inconvenient. Most participants said that between 15 to 30 minutes would be a good duration. Having sessions by phone had mixed reactions, with many saying they preferred face-to-face and privacy from a clinic, while others saw value in the convenience: "*You get to speak to a real person, you can do it from the comfort of your own home*" (Female, 21-25 years).

4.4.4 Patient discrete choice experiment

A total of 368 eligible patients completed the questionnaire, and 90% (331/368) completed all 12 DCE questions, resulting in 21,495 DCE observations overall. Of respondents, 43% were MSM and 50% were young people; compared to GUMCADv2 data from the clinics during recruitment, the sample was broadly demographically representative although there were slightly higher young MSM (16-25 years) and lower MSM aged 26-50. 52% of the sample was recruited from Brighton, 62% were born in the UK and 59% were male; 6 respondents identified as transgender. 46% of respondents have had a previous STI diagnosis, with 22% having three or more STI tests in the last 12-months, and 22% having had no tests.

Twenty percent of respondents (71/368) chose one particular intervention consistently (**Table 19**). However, there was minimal evidence to suggest that a particular attribute level dominated participants choices, only a small proportion of respondents always chose the option with the shortest duration (up to 15 minutes, <1%), the fewest number of session (one, <1%), sessions organised by nurses (<1%) or by other health care professionals (<1%). These findings suggest that respondents were 'trading' between different intervention options, which is an important requisite of DCE studies to be useful.

Table 19: Dominant responses from 368 participants

Choice	**N (%)**
Talking	28 (7.6)
Online 1:1	1 (0.3)
Online group	2 (0.5)
Email or text	34 (9.2)
Opt out	6 (1.6)

Conditional (fixed-effects) logistic regression (CLOGIT) analysis

'Talking' was chosen as the most preferred intervention option on 40% of occasions. The next most frequently chosen option (27% of responses) was the 'email / text' based design. The opt-out option was preferred on <10% of occasions (**Table 20**).

The CLOGIT model explained more of the variation in the data than a model with no independent variables (likelihood ratio chi-square test, p<0.0001). McFadden's pseudo R^2 was 0.13, indicating that the model fitted the data moderately well [125]. It also predicted 42% of choices correctly and the signs on the model coefficients were logical, offering a degree of plausibility to the underlying model (e.g. people preferred shorter to longer sessions).

The analysis showed that respondents generally preferred interventions over 'opting out' (**Table 21**), with 'talking' interventions the most clearly favoured option (OR 1.45; 95%CI 1.35, 1.57 versus 'email or text'). Face-to-face group sessions were generally less preferred to individual face-to-face sessions (OR 0.66; 95%CI: 0.57, 0.78) or to 'one-to-one phone calls' although the latter comparison did not achieve statistical significance (OR 0.87; 95%CI 0.73, 1.02). Respondents generally preferred fewer sessions to more sessions, and shorter sessions were more highly valued than longer sessions. Respondents indicated a strong preference for sessions to be facilitated by healthcare providers

than peers (OR 0.53; 95%CI 0.46, 0.60), but they did not express a clear preference on the type of health care professional.

Table 20: Actual versus predicted results

Choices	Actual N (%)	Predicted N (%)	
		CLOGIT	LCM
Talking	1,740 (40.5)	3,225 (75.0)	2,071 (62.5)
Online 1:1	547 (12.7)	0	179 (5.4)
Online group	519 (12.1)	0	35 (1.0)
Email or text	1,148 (26.7)	1,074 (25.0)	856 (25.8)
Opt out	345 (8.0)	0	171 (5.2)
Total	4,229	4,229	3,312*

*The latent class model (LCM) only includes responses where demographic data were complete

Table 21: CLOGIT results

	Dummy coded			Effects coded		
	ORs	95% CIs	p-value	ORs	95% CIs	p-value
Online Group*	-	-	-	0.42	0.38, 0.47	<0.001
Online 1:1*	-	-	-	0.44	0.40, 0.49	<0.001
Talking*	-	-	-	1.45	1.35, 1.57	<0.001
None*	-	-	-	0.30	0.26, 1.34	<0.001
F2F Group	-	-	-	0.66	0.57, 0.78	<0.001
1:1 Phone	0.87	0.74, 1.02	0.08	-	-	-
Sessions 2 to 3	0.76	0.68, 0.84	<0.001	-	-	-
Sessions 4 to 6	0.60	0.54, 0.66	<0.001	-	-	-
15 to 30 mins	0.85	0.77, 0.93	0.001	-	-	-
30 to 60 mins	0.59	0.53, 0.66	<0.001	-	-	-
Nurse	1.01	0.90, 1.15	0.76	-	-	-
Peer	0.53	0.46, 0.60	<0.001	-	-	-

*Alternative specific constants indicating the strength of preference for individual labels relative to 'emails / texts'

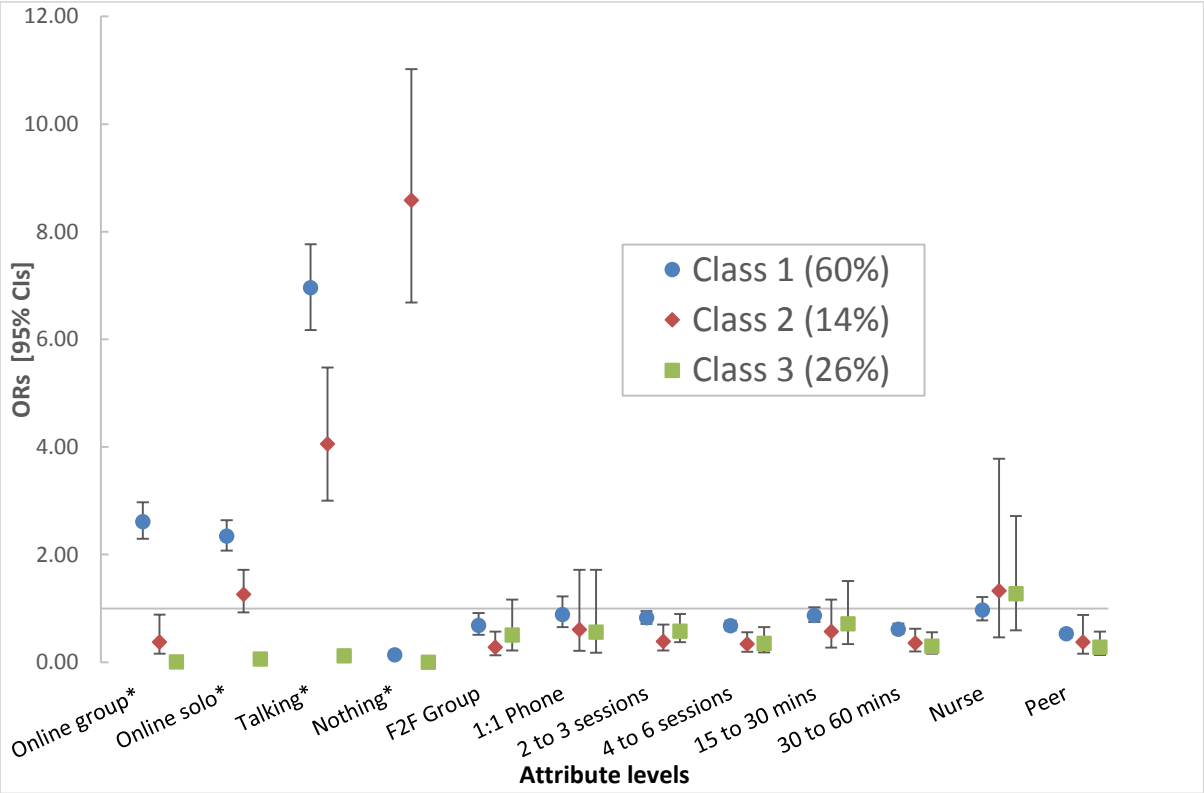
Latent class model (LCM)

Three classes were identified for the LCM. It predicted a higher proportion of correct choices than the CLOGIT analysis, 73% (2,419/3,312) and was more flexible in terms of the options it predicted. None of the sociodemographic variables were predictive of class membership, and were therefore omitted from the final model.

Participants in the classes were similar in how they valued the number and length of sessions, the choice of facilitator and whether or not meetings were one-to-one or group based. However, they differed in terms of their preferred intervention method (

Figure 5). Participants who were more likely to be in class 1 (60%) favoured 'talking' interventions, although all other options were preferred to 'nothing'. Those who were more likely to be in class 2 (14%) had a general preference for 'opting out', although their next strongest preference was also for 'talking' interventions. Respondents who were more likely to be in class 3 (26%) demonstrated a preference for 'email or text' based interventions compared to all other options.

Figure 5: Latent class model results



*Indicates ORs are effects coded, otherwise they are dummy coded; label percentages indicate the proportion of respondents likely to be in each class; log likelihood -3,547; McFadden's pseudo R2 = 0.33

4.5 Discussion

We conducted a mixed method assessment of current triage and sexual risk reduction interventions offered through sexual health clinics and the acceptability and feasibility of the brief interventions identified in the literature review. We found agreement between healthcare providers and service users in terms of intervention acceptability and preferences, and identified key barriers and potential opportunities related to the delivery of brief behavioural interventions in SH clinics.

4.5.1 Current practice

We found that most services at the time of interview and the web-survey (September 2015 – June 2016) reported to offer some form of sexual risk reduction interventions. Most of these took the form of brief one-to-one sessions conducted in clinics, delivered by health advisors in GUM clinics and nurses in Brook clinics. The smaller level-2 service staff, such as in enhanced GP services, reported seeing mostly uncomplicated and low-risk patients and referral to GUM services was the primary approach to intervention. In addition, clinics who did not currently report offering brief one-to-one sessions viewed them as a desirable intervention, with the main barriers being resourcing (trained staff, and staff time).This is in-line with NICE recommendations that high risk patients should be offered brief sessions.[117] Brief one-to-ones were seen by HCPs as being effective, acceptable to patients and allowed for tailoring of interventions; notably, patients concurred that the 'human factor' and tailoring of a one-to-one was important.

Similarly, three quarters of clinics in the web-survey reported conducting some form of triaging of patients based on sexual risk. However, no service reported using a standardised triage based on risk modelling, as we proposed in this study, and triaging embedded into EPR systems was again not common. As triaging is already routine practice, this resulted in many HCPs seeing it as acceptable; this also meant that many HCPs commented that they did not see the point of a model based triage. While clinical risk scores, based on predictive modelling of population data, has been implemented in some specialties (e.g. cardiology,[126] intensive care medicine[127]), it has not be rolled-out in sexual health previously. In order to change sexual health clinic pathways to triage based on models rather

than clinical experience or expert opinion, would likely require strong evidence and HCP engagement.

4.5.2 Opportunities

Several opportunities for risk reduction interventions were raised by both HCPs and service users. Firstly, service users showed a preference for having any intervention over having no intervention, with <10% of patients in the DCE opting for no intervention. Similarly, healthcare providers saw the role of sexual health services as prevention, and not just treatment. This supports risk reduction interventions are being acceptable in general.

There was agreement between HCPs and service users around brief one-to-one sessions being generally preferred. During interviews with health advisors, many felt that one-to-one sessions were beneficial to patients, although acknowledged that patient motivation was important, and that they were part of a health advisors role. These 'talking' interventions were the most preferred by service users, based on the DCE, with fewer sessions, shorter sessions and healthcare provider facilitation being preferred. As clinic resources were raised as a potential challenge to delivery of interventions, conducting a single brief session would suit both service providers and users.

Again, digital interventions were seen as favourable by both service providers and users, although reasoning for finding this intervention type acceptable differed. HCPs highlighted the benefits of digital interventions as not being resource intensive and perceived patient preference. Service users highlighted the convenience of online interventions, and many reported having gone online to find information before attending the clinic.

4.5.3 Barriers

The main barriers raised by HCPs revolved around resourcing and patient motivation, while the key concerns of service users related to privacy and the need or usefulness of an intervention. During the course of this study, changes to commissioning of sexual health services were on-going, with an overall decrease in sexual health service funding nationally. These decreases were not consistent across local authorities, with some reductions in services as high as 20%, alongside an overall increase in GUM attendances.[128, 129] One area which was highlighted as suffering from these cuts to

funding is a reduction in the number of health advisor positions within GUM clinics. The role of health advisors includes partner notification as well as delivering sexual risk reduction interventions. At the time of data collection, services highlighted a lack of staff time and a lack of trained staff in motivational interviewing (MI) as key barriers to delivering risk reduction interventions. With on-going cuts to funds and services, it could be anticipated that these resource constraints persist and even increase, making a currently feasible intervention unfeasible.

The need for privacy was crucial for service users, and this was reflected in the preferences for intervention types (i.e. group, social media and peer led interventions being less favourable). Also important to service users was trust in healthcare providers, and the need for any interventions, especially digital interventions, to be seen as NHS supported or endorsed. This is similar to other studies, who have found that trust of online resources is important to patients,[130, 131] and therefore any digital intervention would need to be seen as trust-worthy. Based on the literature review in WP1 (Chapter 2), none of the digital interventions were developed in the UK or within the NHS. This may prove a barrier to service user engagement if they deem these digital interventions as untrustworthy.

Many clinics reported having EPR systems (86%); however types of system was not universal which may prove a challenge for implementing a standardised, model-based triage approach. EPR providers were diverse, and there were different clinic experiences in adapting these systems. In order to trial an EPR based triage adaptations would need to be made to multiple systems and would be limited to clinics with functioning systems – a potential bias.

Based on the clinic staff interviewed and web-survey responses, we observed a lot of heterogeneity in current services offered, triaging pathways and resourcing. The aim of this project was to determine feasibility of delivering a package of brief behavioural interventions within existing resources in a sexual health clinic setting. Therefore, a key barrier that we can anticipate in determining feasibility is whether different types of services (e.g. level-3 and level-2) and services commissioned by different local authorities, which have different funding structures, will be able to deliver these types of interventions. This would be both a challenge to intervention delivery, as well as intervention evaluation.

4.5.4 Strengths and Limitations

In both service user and service provider interviews, we reached data saturation regarding intervention opportunities and barriers, despite not reaching the targeted sample of 30 interviews with providers. We were unable to recruit the pre-determined number of level-2 providers, and therefore this service type had less representation that we had planned. The interviews with providers and service users were conducted by three female researchers, which may have influenced the responses, especially amongst MSM or young men. However, we saw agreement between reasons for preferences between young women, men and MSM, and also with service providers. We also saw agreement between the qualitative interviews and the quantitative surveys conducted (triangulation), adding strength to our conclusions.

The response rate for the web-survey was poor, and therefor the results may not representative of sexual health services nationally. We attempted several methods to improve the response rate to the survey, including personalised emails and dissemination at a national sexual health conference. Neither of these approaches resulted in significantly increased responses. We contacted clinics directly by email, using a list of contacts provided by PHE and supplemented by a list compiled during a PhD project. We found that many of the email addresses were no longer in use as staff had moved on, that the person indicated was not an appropriate primary contact for the clinic or there was no contact email available. Particular examples of no contact being possible were services which had been tendered by local authorities to private companies or charities (e.g. all services run by Virgin Care). Therefore, several clinical services were unlikely to have been reached, and these may not be representative of other services (e.g. tendered to a private provider or with high staff turnover).

A limitation of the DCE was the ASC odds ratios were generally large in comparison to the attribute levels. This suggests either the intervention characteristics are generally less important to people than the overall format or important attributes and levels were omitted from the design. The attributes and levels were selected on the basis of the qualitative interviews, and therefore based on evidence. We chose not to estimate whether people were more willing to, for example, spend 30 minutes talking with someone than answering questions online when all other factors were held constant (so called alternative specific parameters). This meant that the estimated parameters, such as the duration of each session, were common across the intervention options. However, it is possible that people would value their time differently depending on the intervention type that they are considering. Third, a number of options, such as having videos in clinics and distributing leaflets containing health advice, were excluded from the final DCE design, despite being in the literature

review. Videos were omitted based on the interviews and therefore the results of the DCE are driven by the validity of the findings from the service user interviews.

4.6 Conclusion

Clinics across England, at the time of data collection, offered a range of risk reduction interventions, with one-to-one motivational interviewing being the most common and most desired service on offer. However, contrary to guidelines, high risk individuals were not being provided with additional risk reduction interventions uniformly, and we found a high level of heterogeneity between services. We found similar preferences and concerns raised by providers and service users about different intervention formats. One-to-one sessions were viewed favourably as an intervention format, with the ability for tailoring being very important. This was followed by digital intervention approaches, which were seen as convenient. Videos, which were found to be effective in reducing STIs and risky behaviours and increasing testing in the systematic review, were viewed with mixed feelings by both providers and service users. Finally, peer-based interventions were not popular, both for logistical reasons by providers and privacy concerns by service users.

Chapter 5: Work Package 4 – Choosing and adapting the components of the intervention

5.1 Background

As anticipated in the methodological plan (**Figure 6**), at this stage in the project the following had been completed: obtaining the views of stakeholders, including service users and staff who deliver interventions; conducting a review of available interventions. We had information as to what interventions were potentially acceptable, practically feasible and sustainable over time.[34]

Having completed work packages 1, 2 and 3 we had the basis for the next step in the IM process, to complete the intervention selection. This would allow the manualisation of the one-to-one component of the intervention package, although as discussed above the digital intervention was not immediately available.

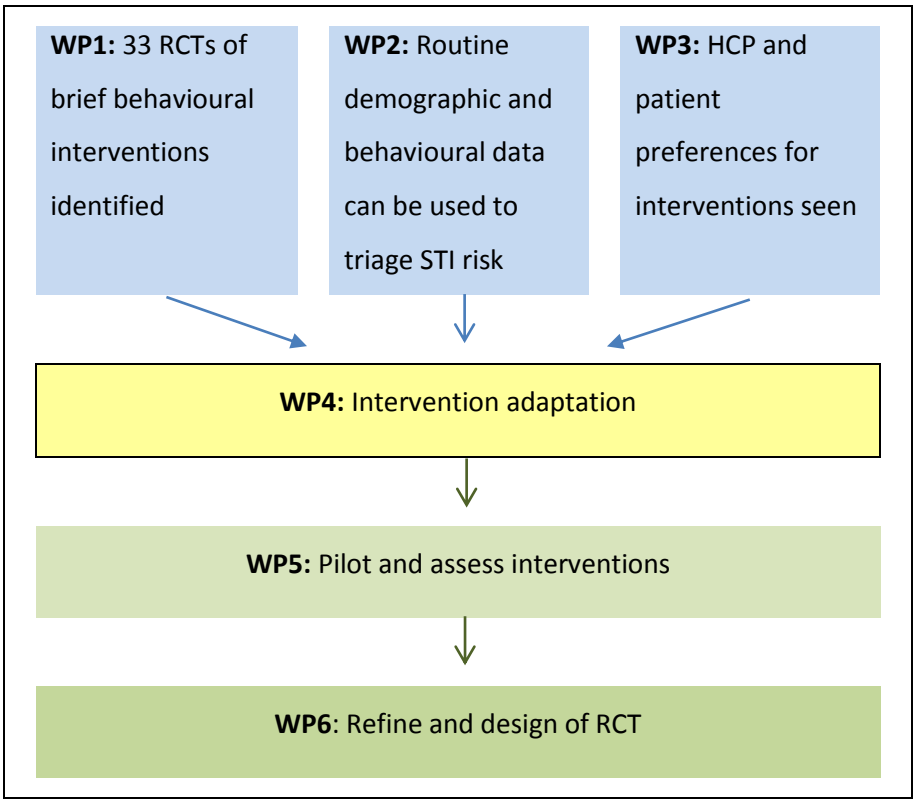


Figure 6: Summary of the work packages contributing to the Intervention Mapping process

5.2 Aim

The aim of this work package was to select, adapt, if required, and manualise an evidence-based suite of interventions that could be combined and delivered as intervention packages to meet individual needs.

5.3 Method

5.3.1 Intervention mapping

This work package brought together the three central steps in the IM, as set out below:

1. Mapping of intervention objectives (i.e. main outcomes) onto psychological, behavioural and environmental determinants or change processes
2. Selecting techniques and strategies to modify the determinants of behaviour based on an understanding of change processes
3. Selection and construction of intervention components and materials

The process had begun with the systematic review (Chapter 2 - WP1), which was used to identify potentially effective intervention components and change mechanisms that may be critical to intervention effectiveness. We identified pre-existing intervention materials which appeared to be effective in reducing STIs and risky sexual behaviour that would be appropriate for UK clinic settings in order to identify 'best bet' techniques and strategies. Findings from WP3 (Chapter 4), from both service providers and users, were used to prioritise intervention approaches and components according to preference, likely engagement and pragmatic resource constraints.

Decisions on the intervention package design and components were made through a series of face-to-face group discussions with the intervention development team (CL, CA, AR, MS, CK, LC, JB, SA and AP), and feedback sought from the PPI group. Three meetings were held as part of this iterative adaptation process, supported by on-going broader discussion with the PSC and PMG.

5.3.2 Service user input

Focus group discussions and semi-structured interviews were conducted with service users, to present candidate interventions and stimulate discussions about: how best to adapt to each group;

feasibility of delivery; likely uptake - and therefore inform the on-going IM process. Candidate interventions for discussion were shortlisted by the intervention development team and shared with the PPI group prior to seeking service user input.

Participant selection: We used a sampling framework, with quota sampling based on sexual orientation, age and gender (including MSM and young people) to gain a broad range of opinions. Four groups were defined: MSM <25 years, MSM > 25years, young heterosexual women, young heterosexual men. Approximately 6-8 participants (n=24-32 in total) were invited to attend for each group.

Recruitment: Participants were recruited from the sexual health service and community settings through posters and leaflets for group discussions. Young heterosexual men were purposefully approached and recruited from SH clinics for individual interviews due to lack of uptake for group discussions. All participants were recruited in Brighton for pragmatic reasons.

Data Collection: Written consent was taken prior to the focus group discussions or interviews starting, and all discussions were anonymous. Each FGD was planned to last 45-60 minutes. Discussions were facilitated by two researchers trained in focus group methodology and were transcribed verbatim. Interviews were planned to be 30 minutes, and were conducted by a single researcher. Patient participants received £20 as recompense in line with current practice.

Analysis: We used the same analysis approach as described in Chapter 4 (content analysis, using a framework approach).

5.3.3 Manualisation

The intervention package was manualised to define specific and replicable modes of delivery with underlying behaviour change mechanisms. As there is a need to translate effective behaviour change interventions from research settings to clinical practice, the manual provides recommendations for implementation in a clinical context, such as role play examples. A training plan was developed as part of the intervention manual in collaboration with clinical staff.

The manual was shared with the management team, PPI and steering committee for feedback, and shared with clinical staff from MMC, Archway, Claude Nicol and Brook services for feedback.

5.4 Results

5.4.1 Selecting intervention components

Intervention types were selected, using both the preferences of service providers and users presented in WP3 (Chapter 4), and prioritising behaviour change needs according to the overall objective of adapting a package of interventions that would lead to a reduction in STIs. The conclusions of the prior work, that set the scene for this stage in the project were summarised as follows:

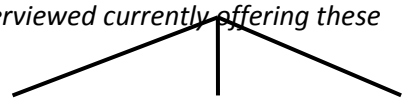
- There is evidence that a range of intervention formats, including brief motivational interviewing sessions, digital interventions, educational videos and home testing kits, can lead to moderate reductions in STIs and risky sexual behaviours.
- Delivery of sexual health promotion tailored to risk was mostly acceptable to providers and patients, and model-based triage algorithms showed moderate discrimination.
- One-to-one talking and online interventions were acceptable to service users and seen as feasible by HCPs, however resource limitations favoured fewer and shorter sessions (brief behaviour change interventions [BBCI]).
- Waiting room videos, group sessions and peer-led interventions were undesirable and posed resource and pragmatic challenges.

Based on these broad conclusions this part of the IM process focussed on one-to-one brief sessions only for patients considered to be at higher risk, as this would be resource intensive; and a digital intervention for all patients regardless of risk, as a low-resource intervention. Evidence generated to this point suggested this approach would be both acceptable and feasible within the current NHS sexual health environment. Further refinement and adaptation of existing interventions is presented below.

<u>Brief one-to-one consultation</u>

Reasons for choosing this intervention included:

- *One of the effective approaches identified in the WP1 systematic review*
- *Clear front runner from the process of WP3*
- *Already in place with most of the clinics interviewed currently offering these*



- *Most participants had favourable opinions about it*
- *Needed to be conducted in a personal and private space*

For MSM, there were three effective trials which used a one-to-one approach, with counselling, motivational interviewing (MI) and personalised cognitive counselling.[52, 72, 73] For young people, two effective interventions used this approach, and one trial included both young people and MSM.[54, 55] Of these five effective trials, the intervention manuals were available for three. Through round table discussion, the conclusions from WP3 were used to refine and select the intervention components from these trials to make decisions about the format and content of sessions. For example, personalisation was considered important to patients and therefore this influenced the decision as to how the session would be structured. We decided the one-to-one approach would use the most appropriate components of all the available manuals for both MSM and young people, and apply these to the needs of both groups. This was based on the finding that generally the needs, risk perception motivations and preferences for delivery were similar between young people and MSM. It also supports the flexible nature of the one-to-one approach.

In the interests of equitable delivery, the intervention was designed to be offered to all service users at high risk, regardless of their motivational assessment, a key barrier to delivery raised by providers and service users. The focus of the sessions would then initially be on identifying 'what aims need to be achieved in this session and how to do it', including a checklist of conversation topics and their level of motivation. Consultation tasks might include risk assessment (e.g. patients' individual risk level, the kind of problems they encounter) and provide normative or attitudinal information based on their risks. If the person is already motivated, i.e. understands their risks and wants to change, then this process could be skipped and refocussed on 'what can you do', e.g. condom use. The sessions will draw on motivational interviewing principles but not attempt to deliver motivational interviewing *per se.* The lack of trained staff time was a key barrier to delivering interventions. It was therefore concluded that the intervention should be consistent with MI principles, but without requiring intensive MI skills training. This would make it more likely to be feasible.

We sought service user input on the duration and proposed that the intervention would be a single session, designed to last 20-45 minutes, dependent on need and motivation. The decision to have a single session was based on the need for the intervention to be pragmatic, able to be delivered within existing resources. Service-user also suggested that multiple sessions would be a barrier to patient attendance and engagement. We acknowledge that service users may be referred for health promotion or partner notification on future clinic visits; even though we decided on a single session, we planned for these to be adaptable and that additional booster sessions could be offered through

the use of action plans to be included in patients' records on an EPR system. These decisions and the overall design attempt to *standardise* what many HCPs reported they were already doing and adds evidence-based structured elements to enhance this.

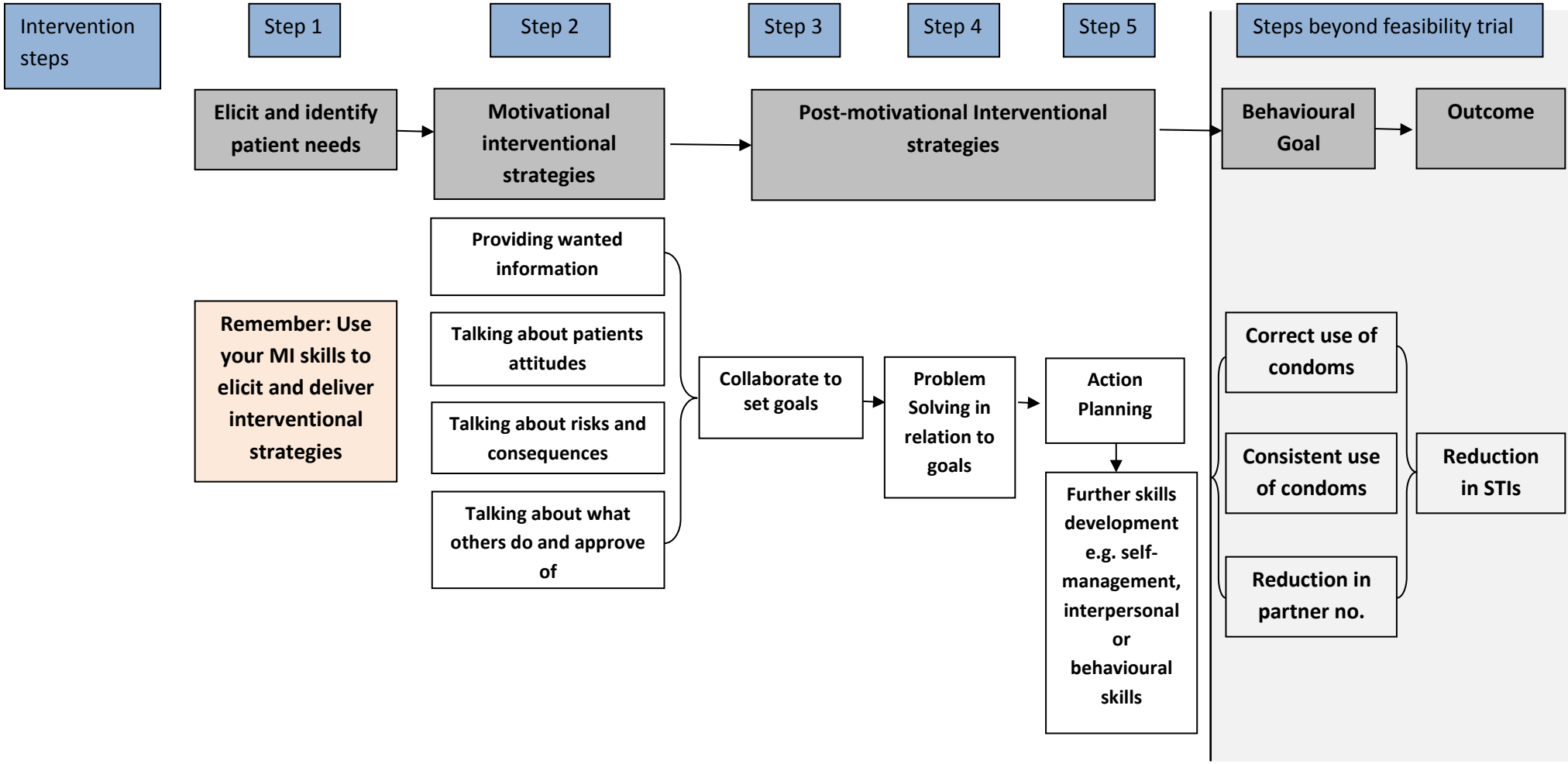
Motivational Interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion. We prioritised a focus on listening for Change Talk within Motivational Interviewing (DARN-C).[132] Identifying and working with patients' change talk is essential for moving from exploration and motivation to directional change. The consultation was not intended to add additional consultations to the clinic service, but rather to provide a way of structuring usual discussions with high-risk clinic attendees as identified in a standardised way by the triage algorithm.

Brief one-to-one manualisation

In order to provide a pragmatic, effective and time-efficient intervention, the one-to-one consultation was structured to suit HAs existing experience with MI by providing a sequence of five linked key steps (Figure 7) that target specific needs and provides a menu of effective intervention strategies (Box 2). The five steps are:

- **Step 1**: Eliciting and identifying patient's current needs
- **Step 2**: Matching needs to any of the motivational intervention strategies we have provided; for example, using supplemented MI techniques to: provide information; talk about the patients attitudes; talk about risks and consequences; and /or talk about what others do and approve of.
- **Step 3:** Collaborating with the patient to set specific goals
- **Step 4**: Engaging the patient in barrier identification and problem solving in relation to their goals (overcoming barriers)
- **Step 5:** Setting specific action plans and discussing self-management approaches helpful to goal enactment and further skills development such as: Increasing self-efficacy/ ability; enhancing condom use skills and/or increasing self-management using If-Then planning.

Figure 7: Santé Task List - Leading the patient through change - The 5 step pathway for Young People and MSM (based on strategies described in Box 2)



Digital online intervention:

Reasons for choosing this intervention type included:

- *One of the effective intervention types identified in the systematic review*
- *Favourable to service providers due to the limited demand on available resources*
- *Favourable to service users due to the convenience, however participants were worried about discretion of an app on their phone and therefore generally preferred websites*
- *Some clinics already refer participants to websites and/or are in the process of developing digital services.*

Intervention Mapping identified effective trials that used some form of digital intervention: three trials that were effective in young people, and five that were effective in MSM. However, of these 8 trials only two had any intervention materials available (**Figure 8**). None of the effective interventions identified in WP1 are currently available online. Downs et al. was developed in the US and used videos to present relationships and sexual health education, but at the time of our study this webpage was being updated and required individual user-fees for access [57]. The need to adapt to a UK NHS setting, individual user-fees, and cultural differences in the content were barriers for use. The second intervention with available content was Mevissen et al. which consisted of a virtual clinic consultation [69]. However, the virtual clinic was developed in the Netherlands; adaptation would have required considerable resources to translate into English and the NHS setting, and was not available free for research use.

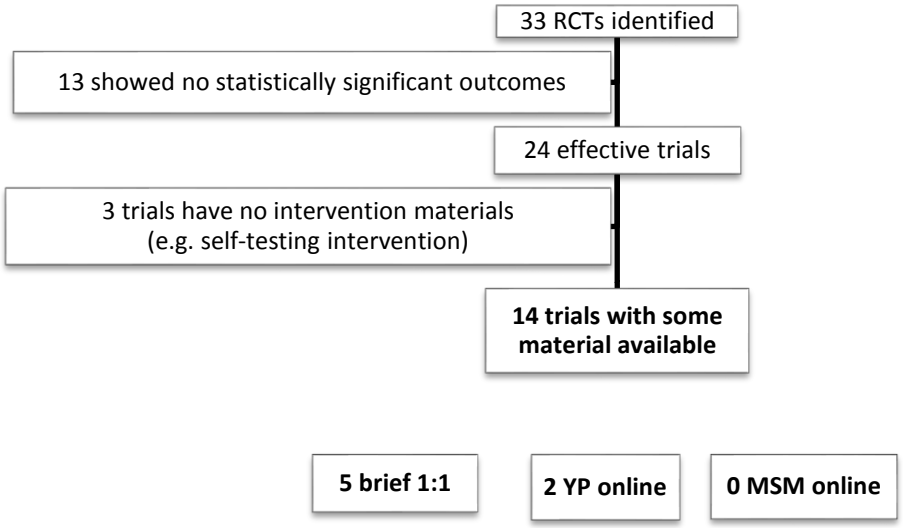


Figure 8: Summary of RCTs available for adaptation in the intervention mapping process

Therefore, there were no evidence-based digital interventions which could be used 'off the shelf'. We consequently decided to develop a webpage that could function as a portal to selected web-resources, and be piloted to measure acceptability and engagement. But this would not be an evidence-based risk reduction intervention. We decided this would include customised links to trusted web resources, which would tailor content to users via brief demographic screening questions, as the personal aspect was important to service users. Place-holders from legitimate bodies (e.g. NHS Choices) were discussed for inclusion, and we sought recommendations from healthcare providers and our PPI group. **Figure 9** shows the stand-in screening page which directed patients to the targeted webpages.

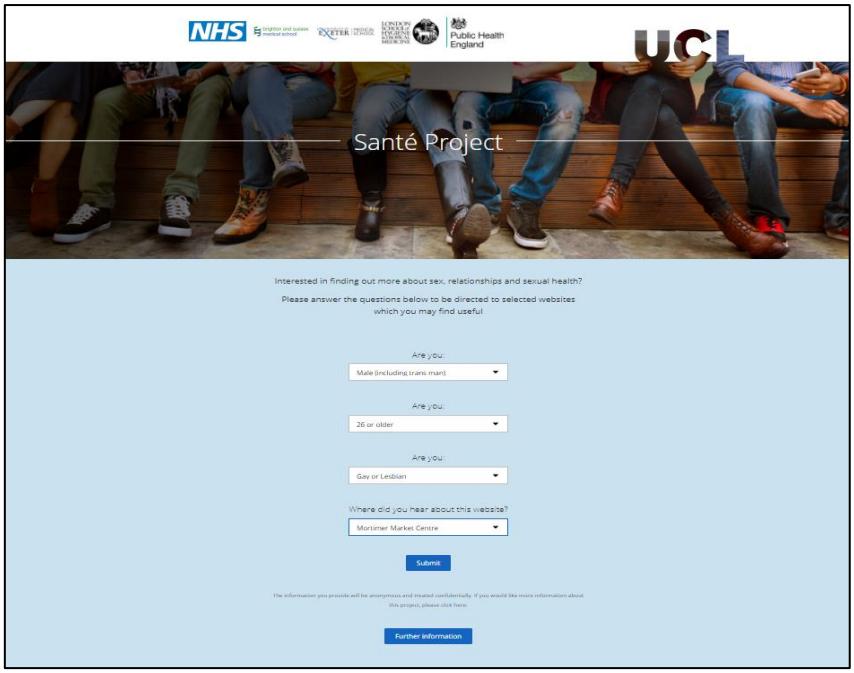


Figure 9: Screening page of the Santé Project custom-built webpage

5.4.2 Intervention refinement and service user feedback

All three aspects of the suite of interventions (triage process, one-to-one intervention, on-line intervention) were detailed in a manual, which presented technical behavioural language in user friendly terms suitable for clinical staff to use with their patients. This was then taken to service user focus groups, health advisors and the PMG for their input. Three focus groups were successfully completed with MSM of all ages and young women, in community settings. We were unable to recruit young heterosexual men to a focus group discussion, therefore we recruited them to semi-structured interviews within the clinic, successfully completing four interviews (Table 22).

Table 22: Summary of service user focus group discussion and interview participants

Group	Number	Age (range)	Sexual orientation	Ethnicity
MSM >25	5	26 – 46	Gay (4) Bisexual (1)	White British (5)
MSM <25	4	18 – 21	Gay (3) Bisexual (1)	White British (4)
Young men	4	16 – 22	Heterosexual (4)	White British (3) Asian (1)

Young women	5	18 – 21	Heterosexual (5)	White British (5)

The process of being triaged, one-to-one MI, and on-line intervention strategies were presented for discussion. Due to the lack of availability of trialled online intervention materials we presented print-outs of website home pages from a range of health promotion web services, which were either of known repute, those recommended by our PPI group, or which had relevant intervention components, alongside those identified from the systematic review. The following webpages were presented to young people: 17 days;[57] Family Planning Association (FPA); the Mix; Brook; NHS Choices. The following were presented to MSM: Terence Higgins Trust (THT); Gay Men Fighting AIDS (GMFA); MenSS;[133] NHS Choices.

Triage process

Most participants felt the offer of a one-to-one intervention could be appropriate and acceptable (especially to '*others'* and '*the younger ones')*, but was contextualised with significant considerations when participants spoke of their own perspectives. At least two participants, both young males, were anxious that the offer of an intervention by an HCP would be '*scary'* and make them feel '*stressed'.* However, such an offer was felt to be more acceptable where a diagnosis underlined the relevance and value of the offer. Where offering an intervention was seen to be normal practice, and was conducted confidentially, this was seen to reduce the anxiety of being specified.

"It depends if you're being singled out or if it's the same for everyone […] If they say, because of X, Y and Z, we think this and it's done in a normal, generic way - that will be more relevant". (MSM, > 25 years group)

The most frequent factor cited as a positive influence on the acceptability of an offer was patients' perception of the value or need for an intervention. Motivating factors were identified or articulated as: perception of risk (and potential impact of infection); an STI diagnosis; and recognition of the clinic's supportive and person-centred approach ('*not just tick a few boxes*'). Across MSM and young people there were repeated expressions of the desire for services that addressed them as individuals with specific and distinct needs. Participants also speculated that the refusal by some patients to engage with personal risks would be a key factor in their response to the offer of an intervention, and this was considered to be a greater concern for younger patients, particularly according to older MSM.

One-to-one consultation:

The offer of a health advisor appointment was considered acceptable by participants, but was only seen to be viable where the patient recognised there was sufficient need or value and that the content would be relevant. Participants expressed little appreciation of the value or purpose of speaking to an HA in the absence of an immediate and explicit need, such as an STI diagnosis.

Younger participants in particular discussed the value and preferences for the timing of an HA intervention. There were diverse and divided opinions across and within groups, but most preferred an intervention to happen straight away, primarily due to other demands on their time. Younger participants also acknowledged the risks of forgetting and not coming back, and not wanting to provide phone numbers to clinics.

Opinions on the ideal length of an HA consultation varied between 20mins and 1 hour, with most participants suggesting ~30mins was appropriate and acceptable. Web-based interaction with health advisors, such as private web-chat or telephone interactions as an alternative to face-to-face appointments was popular with all groups. However, the older MSM group specifically valued speaking one-to-one on the phone, while the younger groups tended to prefer web-chat interactions.

There were mixed responses to the provision of written 'Action Plans' cards as part of an intervention. While the value of clarification and a reminder of key points was identified, some found them '*nannyish'* and several participants suggested that paper versions (even at credit-card size) would be easily lost or discarded due to confidentiality concerns. The provision of the same information via text was recognised as a more effective and preferred method.

<u>Digital online intervention</u>

Participants across all demographics valued the internet as a source of immediate, accessible information, but it was not typically identified as an arena for exploring sexual behaviour. However, participants clearly expressed a desire for interactive content over static information, which would enable them to ask questions specific to their individual needs. The screening page (Figure 9) offered as an example (which asked for age, sex, and sexual orientation) was acceptable and valued by to all groups and interviews. However, any use of log-in details was seen as frustrating and off-putting.

There was a high level of respect for NHS web content across all groups, which was considered reliable and factual. This however went hand-in-hand with a prevalent perception that NHS websites would also be wordy, static and unengaging: *"…the NHS is gloriously boring and matter of fact"* (MSM, >25 years). There was widespread recognition that a risky degree of unreliable

information existed on the Internet; however, the availability of interactive content ('The Mix' and Brook's '*text/web chat*') appeared to override concerns about the reliability of information on these (mostly) unfamiliar sites. Younger participants expressed enthusiasm for the youth-focussed presentation of these sites, and the opportunity to ask questions via text/web-chat appeared to override or displace previously expressed caution about reliability.

The MSM focus groups were shown the following webpages: Terrance Higgins Trust (THT), Gay Men Fighting AIDS (GMFA), NHS Choices ('Sexual health for gay and bisexual men'), Men's Safer Sex (MenSS [133]). Familiarity with some of these sites may have influenced responses, but a key issue of participants being able to personally identify with sites repeatedly appeared. The site for men of any sexual orientation ('MenSS') was largely dismissed due to the prominent image of a woman's lips, but was thought potentially useful to younger bisexual men or men not fully embracing a gay identity: *"This definitely looks predominantly targeted to straight people"* (MSM, >25 years).

Participants appeared less engaged with sites that primarily offered static information, and advocated more dynamic content. The expression of risks as '*slip-ups*' in the MenSS website was appreciated as an alternative to '*risk'* when discussing future experience, and the use of narrative to engage readers was briefly raised in the older MSM group. But even in this group there was little understanding or interest in behaviour-change interventions and most discussion centred on websites as sources of information.

"…that is, for most people, what happens. They slip up. And they may get a reminder to plan, so I go, all right, yes. Because, again, it's for that person to kind of go, 'All right, yes, I've got to plan this'." (MSM, >25 years)

The THT page was largely dismissed and disregarded by MSM participants as being visually too busy and oriented to the charity's fundraising needs: *"THT is clearly about health fundraising. That first page is just saying to me, 'We're a charity', and I wouldn't have even thought about going to there for social advice"* (MSM, >25 years). The GMFA page was acceptable to some, but others (especially younger participants) considered the presentation of a man in underpants too sexual*: "…going back to the idea again, of wanting to be represented; I am put off by the whole beautiful people thing and to me, it just seems too sexy to be educational"* (MSM, >25 years).

The young people were shown the following webpages: Family Planning Association (FPA), Brook, NHS Choices ('*Live Well: Sexual health*' page), The Mix; and Seventeen Days (women only). Preferences did not differ greatly between male and female participants. The FPA site was dismissed in the female group with little comment and the male one-to-one interviews took little notice of this page, referring only to its potential for factual information, and its off-putting status as a charity:

"Like maybe, people will get the wrong idea of, 'Oh I have to donate something to the cause', or something. For me personally if I see something, 'oh charity, oh no, I need to avoid it'" (Young person, male).

Interactive opportunities were more popular than static information pages, and the option of a web-chat facility on the Brook home page was enthusiastically focused on by both men and women, for two key reasons: the flexibility to contact someone at the patient's convenience, and the arms-length method of engagement, which was frequently cited as preferable to meeting an HA:

"*I personally think the web chat would be like the best. Being able to just go straight on it and just have a professional writing back to you, like with an answer because, obviously, you can search all day and still not have an answer for something. So I think that is the best"* (Young people, female).

'The Mix' page was popular with the young female group and most male interviewees. It was seen as being addressed specifically to younger people, and this targeted relationship was a significant motivator of interest. One young male participant was familiar with this site since it was promoted in his school. Positive discussion focussed on key aspects, including its varied content addressing diverse aspects of younger peoples' lives (mental health, STIs, contraception, porn). The homepage tabs: '*Your Voices'* and *'Mental Health'* were each mentioned as a valuable feature, despite their content not being visible in the single page presented to the focus group: "*It's got everything on it. It's not just banging one thing. It's got drugs and alcohol and everything"* (Young people, male).

The home-page of the '17 Days' website, which was shown only to the women's groups, where its narrative format and content was swiftly dismissed for its lack of apparent interaction and immediacy, and the discussion moved on to the value of getting quick answers to STI-related issues.

RE2: "Yes, and they ['17 Days'] could be talking about all stuff that you didn't want to even discuss." RE1: "Yes, you just wanted to know one thing and that could be at the end. Maybe too much to go through" (Young people, female).

5.4.3 Manual refinement

Feedback from service users was combined with feedback from the PPI and the PMG, and the opinions were used to inform the intervention manual, to produce the final version of a manualised intervention package for piloting (Intervention Manual – supplementary material).

<u>Triage</u>

The first step of the intervention package is the application of the triage algorithm presented in WP2 (Chapter 3). To balance clinic resources with sensitivity and specificity, the risk threshold was set to refer approximately 15% of MSM and 5% of young people. The triage was designed to be conducted through the clinic EPR system by any member of clinical staff seeing a patient.

On-line material

Feedback from service users indicated that a screening page used to direct users to more tailored on-line material was acceptable and addressed the desire for services to feel personalised. The proposed links received mixed opinions, so we reviewed the links with further input from the PPI group. The final lists of links included were: (for young people) 'The Mix', 'MenSS' and 'BISH'; and (for MSM) THT, GMFA and NHS Choices. Multiple approaches were proposed for advertising and referring service users to the webpage, which we recommended: sending a link to patients as part of appointment reminder text messages; posters in clinic waiting rooms with the web link up; and encouraging healthcare providers to direct patients to the webpage during appointments. All of these methods were included in the intervention manual.

One-to-one consultation:

The approach proposed to service users during this phase was deemed acceptable in discussions across the wider project team and was not amended based on feedback.

5.5 Discussion

Through an iterative process we summarised and synthesised the evidence from WP1, 2 and 3 and consulted with service users and providers to develop the early stages of an intervention manual. The underlying ethos of the Santé consultation was based on the collaborative, well-researched motivational interviewing approach recommended for use in sexual behaviour change by the NICE, and the Society of Sexual Health Advisers (SSHA). The approach of using an intervention package, where a more resource intensive consultation is focussed on those at higher risk of an STI diagnosis, was designed to be deliverable within existing resources and current clinic structures.

5.5.1 Acceptability of one-to-one

There were two overarching contextual factors that came from the qualitative feedback with service users: that services are private and non-judgemental, and that content was something participants

felt they could identify with. The one-to-one consultation was designed to be adaptable to differing patient needs and motivations, therefore addressing the desire for services to feel personalised and tailored. However, a contradiction was identified with the offer of a health promotion appointment with a health advisor sometimes being off-putting if it was seen to specify the individual patient. Systematic triaging, which could be viewed as '*box-ticking'* was off-putting where it was seen as impersonal, and so this raises questions around how triaging could be conducted in a way that indicates the value of a personalised intervention, while also avoiding the anxiety that being specifically targeted could provoke.

5.5.2 Challenges of digital

Despite several digital interventions being included in the systematic review, and both service users and providers showing some preferences for this intervention format, we could not locate any materials that could be used for piloting. Of the two studies trialled with young people that had some materials available, one required individual user-licenses with significant cost implications,[57] and the other had a considerable number of components in Dutch only.[69] Extensive effort was put into contacting authors of other studies that reported effective digital interventions, with the intention of adapting any potential resources to the needs of this study. If the Santé intervention package were to go to a full trial, a digital intervention would need to be developed or currently available options re-visited. A scoping review had found 19 digital interventions for young people that had been tested for effectiveness, raising questions about how to access, evaluate, regulate and sustain such interventions which quickly become obsolete.[28, 134] With digital formats requiring on-going maintenance, software updates and site management, the potential for off-the-shelf approaches to interventions is limited without wider investment and infrastructure.

The feedback from service users about the various examples of online sexual health information and interventions revealed preferences for certain formats, which would be important in the development of future online interventions. Notably, from WP3 service users demonstrated a preference for websites rather than mobile 'apps'. Magazine-style websites that featured sexual health amongst a range of other youth-oriented content (e.g. abortion, family life, friendship, pregnancy, drug/alcohol, parenthood, safe sex) was valued by young male and female participants as appropriate and engaging. It may be that this magazine-style of website was the only format in which younger participants moved beyond a focus on information-finding and considered the potential for explorations of experience and behaviour. Interactive formats, such as webchat (as offered by the Brook website), were preferred by younger groups as they enabled engagement with

services at their convenience, with the additional advantages of personal distance and anonymity provided by the web interface. Charity sexual health websites (THT, FPA) were considered off-putting due to assumptions that these sites were focussed on, or risked, requests for money, and were unlikely to meet their needs. MSM groups stated that over-sexualised presentation of web content (e.g. GMFA) diluted confidence in the content and diminished participants' engagement with the website. Therefore, an interactive resource that contains both information and behaviour change approaches, and has varied but relevant non-sexualised content could be most acceptable to service users.

5.5.3 Limitations

In addition to the limitations discussed with the digital intervention, we were unable to recruit young male heterosexual participants to take part in a focus group discussion. This was especially challenging in the face of cuts to youth services, and after several attempts to recruit individuals and access existing youth groups, this method was replaced with one-to-one interviews, recruited and conducted in STI clinics. In addition, all participants for group discussions and interviews were recruited from Brighton, and therefore their feedback may not be relevant to young people or MSM in London or other parts of England. The decision to recruit from Brighton only was a pragmatic one, with the aim to gain rapid feedback rather than comprehensive feedback on the intervention package. Further service user input on the acceptability of the intervention package was planned for the pilot study (Chapter 6).

5.6 Conclusion

Despite there being multiple trialled interventions with evidence of effectiveness, there were challenges in accessing the required materials to adapt them for piloting. This was particularly notable for online digital interventions, with only two of the digital interventions identified in the review being accessible, and therefore we used stand-in digital content in our pilot study. Both one-to-one consultations and online interventions were in principle acceptable to service-users as approaches to sexual risk reduction. A key feature for MSM and young people was the need for any intervention to be appropriately tailored to their specific needs.

Chapter 6: Work Package 5 – Pilot feasibility trial

6.1 Background

Work packages 1 to 4 aimed to establish whether there are evidence-based brief interventions that could feasibly be adapted for use in sexual health settings in England, and delivered within existing resources. And having done so, that they could be shown to have an impact on high risk behaviour and STI diagnoses (**Figure 10**). We found that both 'talking' interventions, such as brief motivational interviewing sessions, and digital interventions were acceptable to service users, and desirable for healthcare providers, and therefore this was the focus of our intervention mapping process. We developed an intervention manual for the pilot, using co-creation with service users, providers and the project management team.

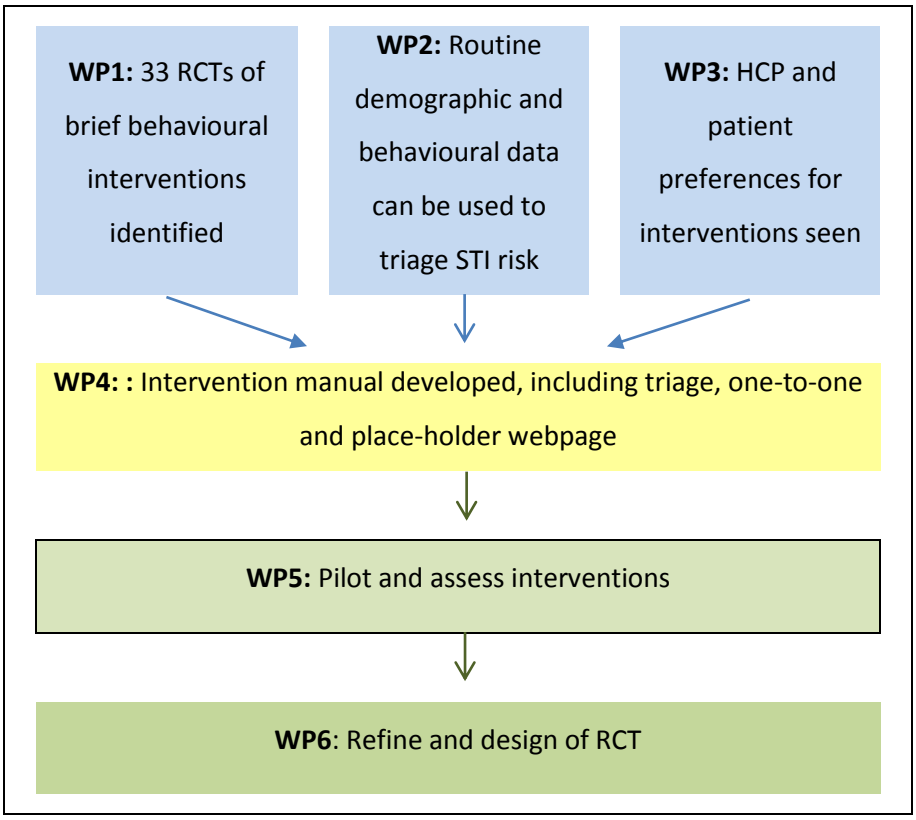


Figure 10: Summary of work packages 1 - 4

A pilot study was used to gather information about the feasibility and acceptability of conducting an RCT, in order to provide information on recruitment, implementation and potential effect sizes.[135, 136] In this case, the pilot was used to investigate whether the adapted one-to-one intervention can be implemented as planned in a routine SH setting and if service users are likely to engage with the intervention package. The proposed methodology of a cluster RCT also needed to be piloted, as this requires both clinic and service user engagement.

6.2 Aim and Objectives

To pilot the intervention package within existing clinic resources, and assess the acceptability and feasibility to both HCPs and service users. Specifically, we aimed to address the following objectives regarding trial and intervention feasibility and acceptability:

Acceptability of the intervention to users and HCP

1. Proportion of eligible service users who attend the clinic that were assigned a score by the triage tool
2. Proportion of those who were classified as high risk who are offered the intervention
3. Proportion of those who were offered the intervention who took up the intervention
4. Proportion who took up the intervention who completed the intervention
5. Reasons for not completing the intervention from the qualitative study of participants
6. Acceptability of the intervention from the qualitative study of the staff

Feasibility of delivering the interventions:

1. The total time spent by service users within the clinical service compared to normal
2. Total number of service users seen and STIs diagnosed, compared to normal
3. Average consultation time compared to normal
4. Number of patients seen by health advisors compared to normal
5. Extra HCP time required for the intervention

Feasibility of obtaining follow-up outcome data

1. Proportion of eligible service users who consented to the follow-up
2. Proportion of eligible service users who were contactable at 6 weeks and complete a questionnaire
3. Proportion who complete follow-up tests

6.3 Method

We conducted a prospective pilot of a cluster RCT (cRCT) across multiple sexual health clinics in England, from March – May 2017 (**Figure 11**). The pilot included implementing the intervention package, follow-up of service users to obtain biological outcome data, and qualitative feedback from service providers and users.

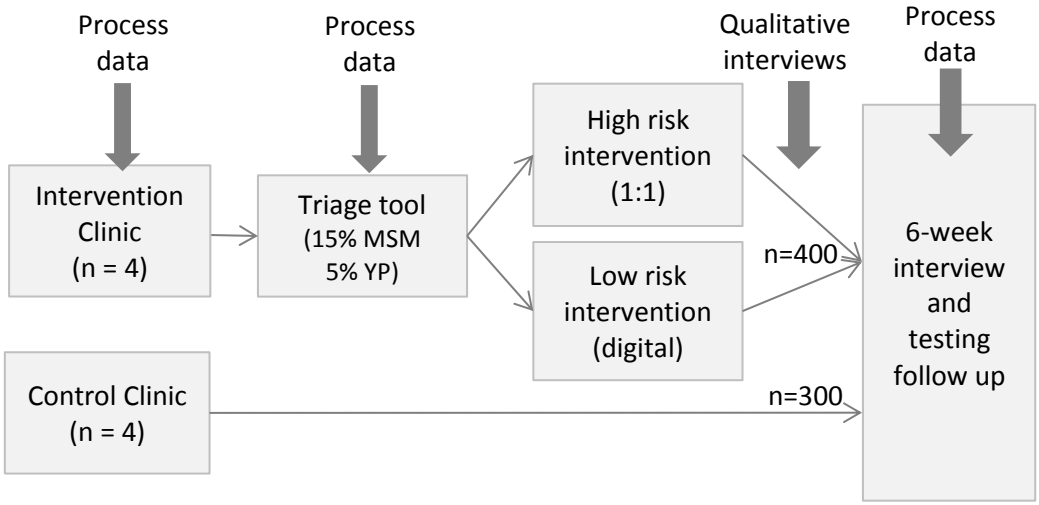


Figure 11: Overview of the pilot trial protocol

6.3.1 Intervention Pilot

We planned to include eight clinics in the pilot, four intervention and four control sites. Clinics were purposefully selected to take part, and include level-2 and level-3 services located in different cities across England. The study was registered on the NIHR Portfolio, which allows sites to volunteer to take part. In a full trial, allocation to intervention or control would be randomised, but was not required in the pilot to determine feasibility.

Participants

All MSM and young people attending the clinics during the pilot period were eligible to be triaged and offered the appropriate intervention. Service users who lacked capacity to self-complete the triage were excluded (e.g. could not read English); however a member of the research team was present to help with any technical barriers to using the triage assessment tool.

Intervention

The intervention consisted of three components, as described in more detail in Chapter 5 (triage, online intervention, one-to-one intervention). Participants in the intervention clinics were triaged using a risk prediction tool, which was self-completed on a stand-alone tablet computer. Their triage result code was printed on a ticket and they were asked by a member of study staff to give the ticket to the healthcare provider they saw. Based on their risk score, participants were eligible to be offered one or both interventions:

High intensity: patients who scored highly in the triage algorithm for sexual risk were eligible to be offered the high intensity intervention. This was a brief 1:1 session with a trained member of the healthcare team (expected to be a health advisor in GUM clinics). This intervention was designed to be delivered in a single session, lasting up to 45 minutes, and on the same day as the participant's clinic visit.

Low intensity: this was offered to all patients, whether they scored above or below the threshold for referral for the high intensity intervention. This was a web-page designed specifically for the pilot trial, containing targeted sexual health information that could be accessed either during the clinic visit or at home later (www.santeproject.com – note this webpage is no longer active).

Service users in control clinics received standard of care, which may have involved the offer of a behavioural intervention, including a consultation with a health advisor that the clinic already provided.

In the intervention clinics, the healthcare provider that patients saw for their appointment could decide whether to refer a 'high risk' patient to the high intensity intervention or not. The triage tool was set to refer approximately 15% of MSM service users and 5% of young people. This meant that MSM with a predicted risk of STI diagnosis >24%, and >22% in young people were classified as high risk, based on the development dataset used in Work Package 2. These thresholds were deemed to be feasible in terms of the numbers of service users being referred, and giving a reasonable balance between sensitivity and specificity.

The project protocol and intervention package was presented to all clinical staff in intervention clinics during a routine staff meeting. Participating health advisors had a training session (designed to be 2 hours) on the intervention manual, including use of role-play.

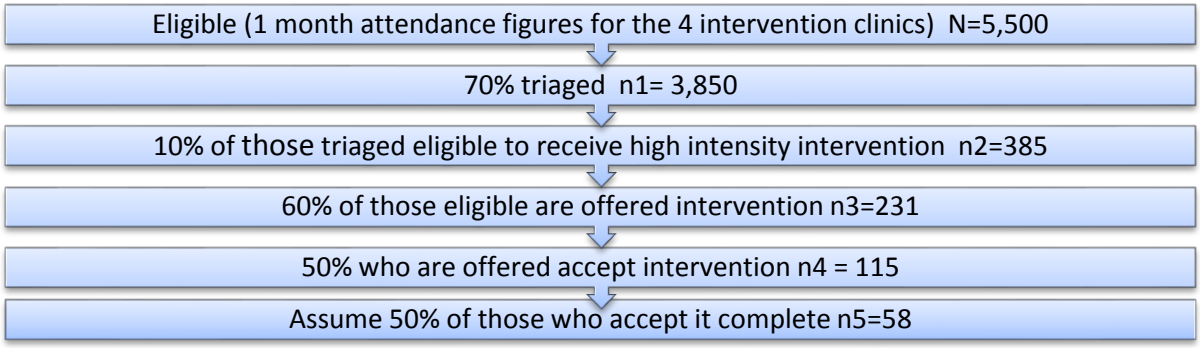
Data collection

Triage data was self-completed by service users, and was collected using Android tablets, through a custom-built ODK Collect form. The same variables were collected as those presented in Table 6. Anonymised data was uploaded to a secure server. Data about the one-to-one intervention process was recorded in the EPR system in Brighton, and on paper forms in Archway. Engagement with the digital component of the intervention package was monitored using Google analytics during the pilot period. Process data for the number of service users attending the clinics during the pilot period, where available, was collected within the clinic existing EPR system.

Sample Size

Based on historical clinic patient data on attendances provided as part of the GUMCAD data return, we estimated that a total of 5500 eligible patients would attend four clinics during the 1-month intervention period (**Figure 12**). Based on 70% of patients in the intervention period being triaged, an average of 10% being eligible for the high intensity intervention, and 60% then offered interventions, we expected 231 patients to be offered the high intensity intervention. Assuming 50% accepted the intervention, and then 50% completed it, we estimated 58 patients would complete the intervention, with an expected 95% confidence interval of the proportion as 44 to 57%. The assumptions for the proportions triaged, offered and accepting the intervention were purposefully conservative to reflect the potential for poor engagement with the trial from HCPs and service users.

Figure 12: Flow chart for patient flow through the clinic



Analysis

We planned to describe the proportion of patients who went through each phase of the intervention process, comparing clinic types and patient demographics, adjusted for clustering at the clinic level. All analyses were conducted in Stata 14.

6.3.2 Interviews and focus group discussions

Telephone interviews with service users were conducted to explore the reasons for not accepting the intervention, or not engaging with the intervention process and how their triage score matched their perception of risk.

Group discussions were held with service providers to explore potential challenges to intervention implementation and any feedback on acceptability.

Participant selection: We sampled young men and women, and MSM who were attending sexual health services and completed the triage process. We sequentially recruited service users who scored 'high risk', aiming to recruit 24 service users across two clinics.

HCPs were purposefully recruited from participating clinics to represent both health advisors and other clinical staff, with two FGDs planned for each participating site.

Recruitment: Service user participants were recruited from participating clinics. They were approached in the clinic waiting room and given a study information sheet to read before deciding to take part. Participants were offered a £20 high-street voucher for taking part. Interviews were either scheduled to take place on the day of recruitment, or scheduled for a future time, by telephone.

Healthcare providers were emailed to invite them to take part in a group discussion. When there was not enough interest to form a group, individual interviews were conducted.

Data collection: Interviews were by phone and group discussions were conducted within the clinical setting. Interviews were designed to last 20 minutes, and the group discussions 45 minutes. Written consent was taken at the point of recruitment for service users and prior to the discussion starting for providers. Interviews and discussions were audio-recorded and then transcribed using a professional service.

Analysis: We used the same analysis methodology as described in Chapter 4.

6.3.3 Follow-up

We recruited a sub-set of patients from intervention and control clinics, to be followed 6-weeks after their clinic visit with a web-survey and STI screen. The STI screen was either through a postal self-sample kit, sent to patient's homes, or patients returned to the clinic for a 'quick check' screen. The screen included chlamydia and gonorrhoea, with a urine sample for men and vaginal swab for women. The web-survey collected information about their recent clinic visit, including any interventions received.

Participant selection: All young people and MSM attending the recruitment clinics during set time periods were eligible for recruitment. There were no sample targets in terms of demographics.

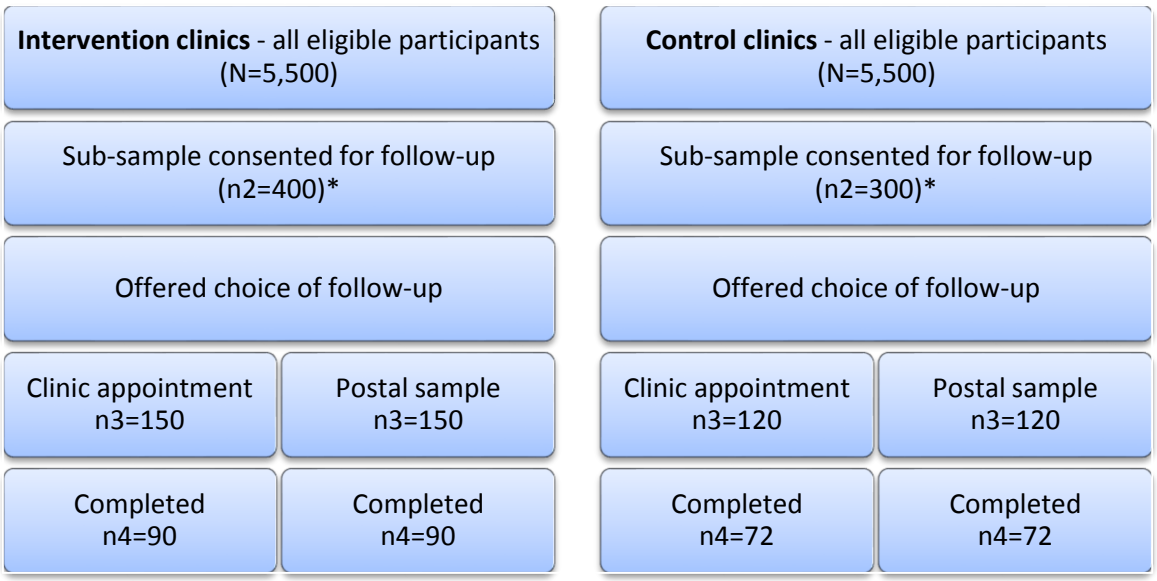
Recruitment: Participants were approached in clinic waiting rooms and given information about the study by a member of the study team or clinic staff. Recruitment was conducted in specified time

blocks at clinics, until enough patients consented. The patient's preference for returning to the clinic or being sent a postal self-sample kit was recorded and patient's self-completed information about their age, ethnicity, sexual orientation and contact details. The clinic patient ID was used as an anonymised study ID that could be linked to clinic records for processing results. The process was standardised across intervention and control clinics, and information posters were displayed in all clinics. A total of 75 and 100 patients were targeted for recruitment from control and intervention clinics, respectively (**Figure 13** – n2).

Data collection: Recruitment data was collected using Android tablets, through a custom-built ODK Collect survey form. Encrypted data was uploaded to a secure server. The follow-up web-survey was created using SnapSurvey, with no identifiable information requested. Patients were emailed the survey link up to 3 times. The follow-up STI screen was either through a postal self-sample, processed by TDL laboratories, or participants returning to clinic. Results were emailed to an NHSMail email account, and patients were sent negative results via text message from a study phone number. Any positive results were sent to the study coordinator at the recruiting clinic for follow-up and treatment according to local protocols. All follow-up data was entered into a Microsoft Access database and processed using Stata 14.

Analysis: We described the frequencies and proportions, by clinic, age group, sex and ethnicity, for each stage of the follow-up. Proportions were compared using chi^2 and multivariable logistic regression.

Figure 13: Sample size for patient follow-up at 6 weeks



*n2 = total for all participating clinics, therefore 400/4 = 100 in intervention clinics and 300/4 = 75 in control clinics.

6.4 Results

6.4.1 Clinic Participation

We planned to include four intervention and four control clinics in the pilot (Figure 14), with all eight sites recruiting patients to the follow-up STI screen, and the four intervention clinics implementing the complete manualised intervention. Inclusion in the pilot study was discussed with 13 potential sites over a six month period. Three sites agreed to be control clinics: Croydon, Durham and Chelsea & Westminster; and three agreed to be intervention clinics: Mortimer Market Centre (MMC, London), Archway (London), and Claude Nicol (Brighton). Both MMC and Claude Nicol have large MSM patient populations, and Archway serves a predominantly young and deprived patient population. At each site, a single site lead was identified to support the implementation, and this was either the clinical lead or a health advisor.

Among the intervention sites, we were unable to pilot the intervention package at MMC despite their initial agreement, and it was only partially piloted at Archway (**Figure 14**). We had discussed the implementation with the clinic lead, health psychologist and health advisors over a six month

period before determining that it was not feasible. Reasons given for the inability to implement the intervention focussed on the lack of staff resources and physical space within the clinic to see patients for a one-to-one session. This had not been raised initially when the sites were selected, but the pilot study period coincided with re-tendering of the sexual health services in London, which has resulted in a substantial reduction in the size of the service commissioned. At MMC, we tried to mitigate the issue of staff-time by offering bank shifts, overtime payments and recruiting temporary health advisors as research assistants. None of these approaches were successful in securing additional resources within the time available for the pilot.

We were unable to include any level-2 services within the pilot. One service provider (Brook) were willing to participate following discussions with their clinical lead and London and South East service manager. We identified 3 potential sites, including both inside and outside of London. In the event, there were insurmountable problems that prevented both piloting the intervention and recruiting patients for follow-up. These included: implementation of a new EPR system; lack of clinic space for recruitment or intervention delivery; lack of staff capacity to deliver the intervention package; lack of clinic capacity to process additional test results; loss of one contract leading to closure of a clinic and relocation of staff. We contacted four alternative level-2 services, all of whom stated they were unable to take part due to concurrent re-commissioning or lack of capacity.

Figure 14: Clinic participation in the pilot feasibility study

*The project was on the CRN portfolio, meaning it was visible to all services who could contact the study coordinator to take part.

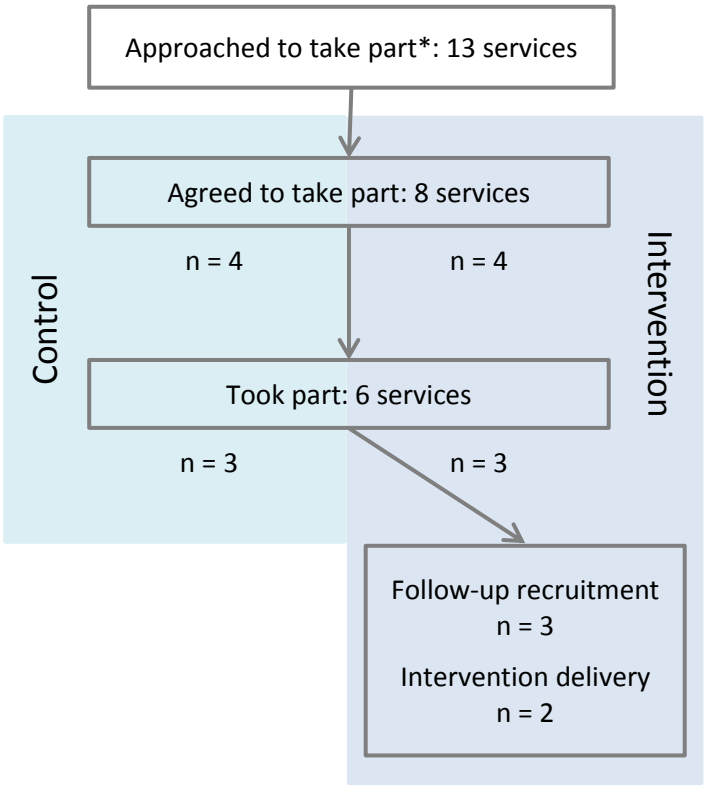
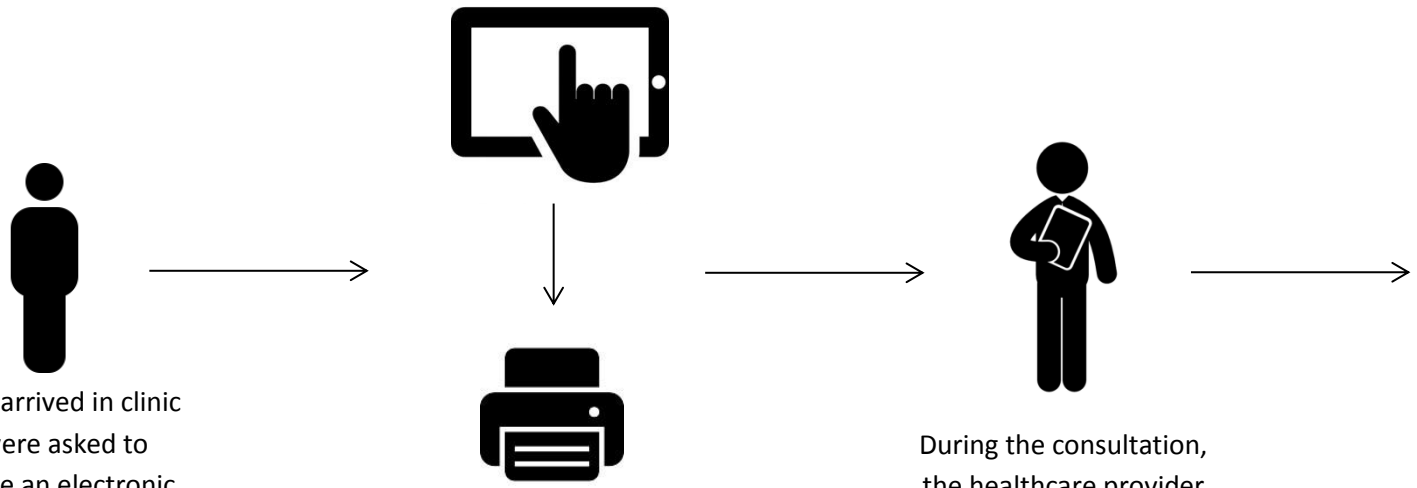


Figure 15: Schematic of the pilot Santé intervention patient pathway



Patients arrived in clinic and were asked to complete an electronic form before they were seen.

The triage algorithm was run on tablets, and for MSM and young people produced a referral recommendation. This was printed for them to take to their consultation (similar to blood pressure).

On the tablet, once the data was filled in, all patients were provided with the Santé website URL.

During the consultation, the healthcare provider checked the patient's print-out, and if it indicated they were at HIGH RISK, offered them a referral to the health advisor.

The triage algorithm aimed to refer 15% of MSM and 5% of young people for these appointments. The HA intervention was an MI based talking intervention.

6.4.2 Intervention Pilot

Triage:

The original proposal aimed to embed the triage tools developed in WP2 within the EPR systems of clinics for the pilot trial. We discussed this proposal with two different EPR software providers (MillCare at Brighton, RioMed at MMC and Archway), but these companies were unable to implement the triage within either of these systems.

In Brighton, the feedback from the EPR provider was that the implementation of a triage tool as we developed would be feasible but would take considerable coding and configuration, and a minimum of 6-months' development and testing. Therefore, we did not pursue adaptation of the EPR at Brighton due to the time constraints. It was also noted that the EPR provider raised concerns over our approach, as despite the triage tool parameters already being collected within the EPR system, the real-time processing would be computationally intensive (e.g. deprivation quintile is derived from a patient's postcode).

At MMC and Archway, the EPR provider indicated that the implementation of the triage within the system was achievable and anticipated three-months to develop and pilot the system. Concerns regarding the coding or configuration were not raised. Over an eight month period the EPR provider developed three iterations of the triage, however none of these were deemed practical, with issues of double data entry, burdensome navigation through the patient record, and the removal of compulsory fields. Therefore, we were unable to pilot test the triage within the EPR system at these sites, and indicates that were this to be pursued then a programme of software development would need to be supported and funded by the NHS provider.

For the purposes of the pilot trial, we developed a stand-alone Android tablet-based system using open source software (ODK Collect). This altered the patient pathway from that originally proposed such that patients self-completed the triage prior to their appointment, rather than the triage being conducted as part of the consultation with a healthcare provider. This system was in place for a month before the pilot began so that it could be integrated into the clinic and to allow providers to become familiar with the study protocol.

The triage tool was completed 1,064 times, representing 16% of patient attendances during the pilot trial period. Sufficient information to complete the triage process was provided by 1,030 (97%) patients, and 612 (59%) were either young or MSM. As study staff asked service users to complete

the triage prior to their clinical appointment, we were unable to distinguish our target groups, and therefore aimed to have all patients take part. A higher proportion of young people were triaged than MSM in both settings (Table 23).

Table 23: Summary of the triage process during the pilot trial

	Brighton (n, %) **Total = 925**	**Archway (n, %)** **Total = 139**
Young people		
Clinic attendances	1,472	365
Triage completed	306 (21%)	50 (14%)
High risk	50 (16%)	17 (34%)
Low risk	256 (84%)	33 (66%)
Attended one-to-one	10 (20%)	3 (18%)
MSM		
Clinic attendances	2,369	88
Triage completed	246 (10%)	10 (11%)
High risk	71 (29%)	2 (20%)
Low risk	175 (71%)	8 (80%)
Attended one-to-one	11 (15%)	1 (50%)

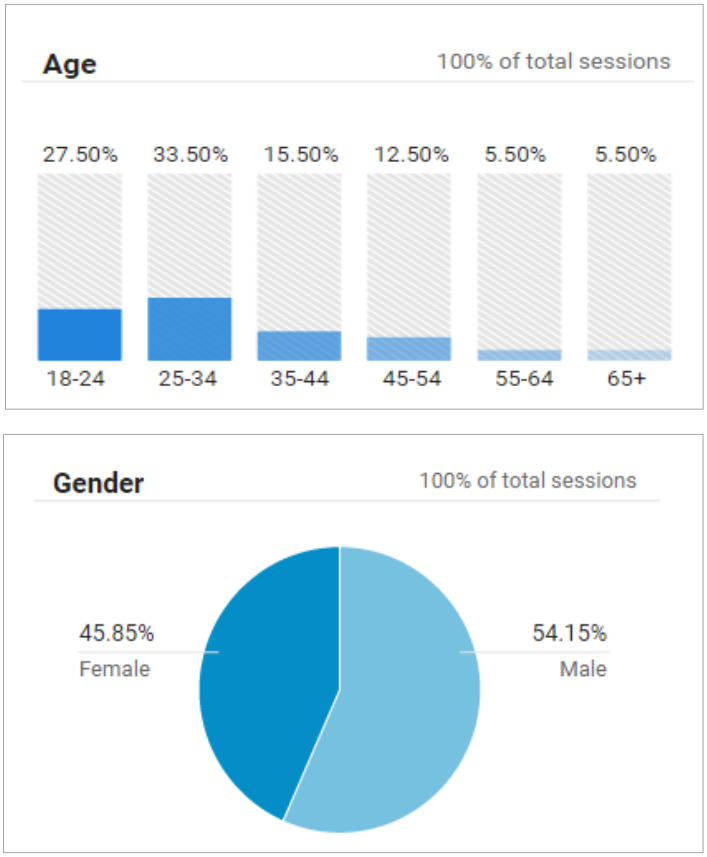
The triage tool was set to a risk referral threshold that we had planned would identify 5% of YP and 15% of MSM to be high-risk, based on the model performance from WP2. However at both sites, the triage identified considerably more than this (Table 23). Notably, there was a higher proportion of high risk young people at Archway clinic and a higher proportion (and attendance in general) of high risk MSM in the Brighton clinic. These risk profiles of the two clinics is not necessarily surprising, and likely reflects that the demographics and sexual history of the pilot trial populations differ from the development dataset. There was also a lower level of missing sexual history and behaviour data from the pilot, compared to the WP2 dataset, and this may have changed the triage tools performance. The threshold for defining a high-risk patient could be adjusted for clinics according to the capacity to provide a high risk intervention, but this poses specific challenges for a standardised approach to triaging.

<u>Santé Webpage:</u>

During the pilot period, the project webpage was advertised in four ways in both pilot clinics: on posters displayed in the clinic waiting rooms; the web address was printed on the triage tickets; HCPs in the clinics were informed about the webpage; it was printed on the action plan cards given during the one-to-one sessions.

A total of 24 unique users visited the webpage during the pilot, of a potential 6,805 patients (0.4%), with one visitor returning. On average, visitors stayed on the webpage for 38 seconds, and stayed on the home page. Two users accessed the webpage using a mobile phone, and all other site visits were from computers. **Figure 16** demonstrates the age and gender of the site visitors.

Figure 16: Age and gender of the Santé Webpage visitors (derived from Google analytics)



<u>One-to-one</u>

At Archway, one HA agreed to work additional bank shifts during the piloting period, meaning we could deliver the intervention package two days a week during May 2017. In Brighton, the HAs implemented the intervention as part of their routine practice from the 2nd May – 2nd June 2017. Training was delivered in two brief (1-hour) sessions at Brighton with the whole HA team present, and in a single session at Archway (1-hour). The training included an overview of the study protocol, explanation of the intervention manual, and brief role-play exercises using the five steps of the one-to-one consultation, and the use of the action plan cards.

In Brighton, the EPR system was adapted to include information about whether the patient had been triaged, the decision on whether the patient was referred for the one-to-one and if they accepted. Of the 552 eligible patients who completed the triage process, records for 168 (30%) were entered into the EPR system, and this was slightly higher for YP than MSM (31% versus 24%, respectively). A total of 21, 0.6% of all potential eligible patients, were recorded as having completed a one-to-one session; this represents an average of one patient a day. However, it is possible that more patients completed the one-to-one but were not recorded in the EPR. In the HA comments recorded within the EPR system, sessions took 5-15 minutes, but this was reported in only a few records. More general comments on the content of the sessions, of which examples are given below, showed that they covered a range of topics and that patients had a range of motivation around behaviour change:

"Has made patient realise that it is important to know potential partners well and use condoms, especially in early stages of a relationship." (YP, Brighton)

"Triaged wrongly as high risk; one episode of UPAI for which he accessed PEP. No other UPAI. No [chemsex]. Consistent condom use and informed" (MSM, Brighton)

"Discussed risk taking as part of PEP discussion. Patient acknowledges risk behaviour and it is usual for him to make decision of knowing partners. Due to alcohol this did not happen this time. Patient not choosing to make changes to this behaviour at this time" (MSM, Brighton)

At Archway, of the 60 eligible patients who completed the triage, 19 (32%) were high risk, and 4 (7%) completed the intervention. The four sessions were recorded as taking approximately 30 minutes each, but the intervention steps and action planning was conducted in only three. The content of the sessions were reported as including condom use, peer pressure around risk behaviours such as drugs and contraception with young people, and PrEP, PEP and general STI knowledge in MSM. Amongst those who were triaged as high risk but did not attend the one-to-one session, reasons for non-attendance included the patients not waiting for the appointment, issues with the referral process in the clinic and healthcare providers not feeling a referral was warranted.

6.4.3 Service user qualitative feedback

A total of sixteen interviews were completed, out of the 24 service users consented (**Table 24; Box 4**). We were unable to complete eight of the planned interviews as participants did not answer our

calls or they declined to take part when we subsequently contacted them. We contacted individuals up to three times, by either phone call or text before deeming them lost to follow-up. Reasons for participants presenting to the sexual health clinic were: routine check (n=7), contraception (n=4), treatment (n=3), and because they were concerned about a recent contact with a sexual partner and their STI results (n=2).

Table 24: Service user participants in pilot study qualitative feedback

	Young people	**MSM**
Location	London = 5 Brighton = 4	London = 2 Brighton = 5
Age	<18 years = 2 18-21 years = 3 22-25 years = 4	<25 years = 3 25-50 years = 3 >50 years = 1
Ethnicity	White = 4 Black = 2 Asian = 1 Mixed = 2	White = 5 Asian = 1 Other = 1

Triage and referral to the one-to-one session:

All the participants were recruited in participating clinics following their completion of the self-triage; participants indicated that the triage process was acceptable, although many appear not to have understood its purpose. Overall, they felt comfortable with the questions being asked (i.e. demographic and recent sexual behaviours), and found that filling in the questions on the tablet computer was straightforward. One of the main advantages was that the tablet was felt to be quick to complete and could save time. The discretion of self-completion was also mentioned but not as a key issue.

Although one participant raised a concern about whether the questions took all the relevant information about sexual risks into account (MSM, >50 years), no one objected to being referred to a health adviser based on the triage tool. However, while conceptually acceptable, there was little evidence that the ticket-based system we piloted in lieu of an integrated EPR-based system was feasible. Only half the participants we interviewed gave the ticket to the HCP they saw - reasons for this failure were: confusion about an unfamiliar process; and forgetting, e.g. *"We're a bit distracted when we're there"* (MSM, >50 years).

There were mixed experiences amongst those participants who successfully passed their triage ticket to the HCP. For example, a young female participant (25 years old) came in for contraception and did not expect to talk about sexual risk. Some patients felt the triage ticket prompted a helpful discussion about new sexual partners and it could result in them agreeing to have an STI test. Others however reported that their HCP did not seem to want the ticket or discuss sexual risk, while others spoke briefly with the HCP about sexual risk: *"I gave it to, like, my doctor, and she, did a little talk on sexual health and stuff"* (Female, 22 years). Patients who did *not* give the tickets to their HCP generally reported discussing sexual risk with their HCP regardless.

Many of the patients who had come for contraception or routine check-ups and neither expected nor were offered any health promotion interventions, such as leaflets or the anticipated referral to a health advisor. Among patients who were referred to a health adviser based on the triage tool, reasons for accepting a referral varied. For example, the opportunity to talk about post-exposure HIV prophylaxis (PEP), or to have a general discussion about sexual health and risk behaviours:

"I found it reassuring that there are services in place that would be, looking out for potential relapses with people that come into that clinic" (MSM, 25-50 years)

"I think that was good because I feel, if I hadn't given her the slip, I might not have been told to go to the health person. I think that was good for me, just to speak to someone else as well" (Female, 18-22 years)

<u>Santé website</u>

While there was no indication that patients found the idea of the Santé website unacceptable, only one of the interview participants (who had also attended the HA one-to-one), had visited the webpage. The young woman who visited the webpage (18 years old) said she went to the website for additional information and was happy to do both a one-to-one and visit a webpage. Other participants reported wanting to find specific information from the internet, and a young woman (21 years old) for example had searched to find out more about her treatment but had not visited the intervention website.

A few participants indicated they might check a website on their phones while waiting for their appointments, but would not go back to it afterwards. However, none of the participants had visited the website using the link advertised on posters in the clinics or the tickets, and most had not noticed the information printed on the ticket. Barriers to this were poor understanding that the ticket contains relevant information, and not having the skills or facility to scan the QR code on their phone. One young woman stated that she might have been interested in checking the website but the HCP took the ticket from her. Participants reported not seeing the posters, among all the

displayed information, and being too distracted or busy reading or talking while they waited. Texting the web-link (e.g. with the appointment reminder) was suggested as a more effective way to promote a webpage.

One-to-one session

Very few of the participants we interviewed were referred to see the HA as intended. Participants who had previous reported experience of one-to-one sessions typically saw them as worthwhile giving them motivation to change and even resulting in behaviour change: *"It was something that I was already thinking but it just pushed a bit more"* (Female, 20 years).

Participants were generally open to the idea of a one-to-one session with a HA. Only one young woman (21 years) said she was always asked to see a health adviser about her drinking and consistently declined as she does not consider it to be a problem. Some participants wanted a clear reason for seeing the health adviser and would be motivated to ask to talk to someone if they had specific questions or concerns. Others thought they would accept the opportunity to talk to a health adviser if it was recommended to them, although this sometimes raised anxious concerns: *"I think I'd be a bit nervous as to why they recommended me to one, but, like, I would go. If they're recommending me to go see one, then I would"* Daniella (Female, 17 years).

Other barriers to attending a HA referral included time and the gender of the HA, e.g. a young woman (25 years) said she would be more inclined to talk to a health adviser if it was quick, and wanting the HA to be the same gender.

Box 4: Case Studies

'Jeff'

Jeff (MSM, 21 years) had come in for his regular three-monthly HIV test and was referred to the health adviser to talk about post-exposure HIV prophylaxis (PEP). He had never seen a health adviser before and was curious and, although he had to wait some time, he wanted to do it then and there. Their conversation covered STIs other than HIV and he decided to have a full STI screen after their discussion. Jeff explained how this clinic visit was very different from usual: *"Because to start with there was the tablet experience, filling in and then getting a ticket and then being informed about the health adviser and then actually talking to that health advisor. Yes, it was really different because usually it would just be going to the room with the doctor and then getting a finger prick done and that's it, yes".* His action plan had included doing some research around STIs and PEP, and he had followed through on this and intended to have regular full screening in future.

'Kelly'

Kelly (female, 18 years) had just been diagnosed with an STI and valued the opportunity to talk to someone, although the health adviser did not feel it was appropriate to do an intervention with her because her anxiety was high: *"So, I was quite happy just to talk to someone and just ask questions about it, because I wasn't really sure. And I had seen a health advisor before, and it was quite helpful".* She had seen a health adviser before to discuss changes she might like to make, although she felt a bit judged, she felt it had changed her mind about what she was doing. On this occasion, speaking to the health adviser helped calm her down and made her realise that everything was okay.

'Emma'

Emma (female, 17 years) had come in for treatment and welcomed the opportunity to see the health adviser and get more information. She had kept her action plan and thought it was a good idea. She thought the discussion was useful and had also visited the website.

6.4.4 Healthcare provider qualitative feedback

We had planned to conduct FGDs with both HAs and other clinical staff from Archway and Brighton to get feedback on how the intervention was implemented and experience from service perspectives. Two group sessions were held in Brighton, including three health advisors and four

other clinical staff. Recruitment from the London clinics was more difficult, with two doctors and one psychologist who had not been directly involved in the triage or the intervention taking part. Their comments remain speculative. An individual interview was conducted with the HA from Archway who had taken part in the pilot.

Triage

The value and effectiveness of the triage algorithm was questioned by most participants, who generally considered this to be a 'blunt' and diluted alternative to the more sensitive interpersonal, face-to-face risk assessment. Among HAs there was suspicion and lack of confidence in the capacity of the triage tool to accurately predict risk or need.

"As a system, I don't think it works and it's not the same as having someone in front of you with it and then, kind of, ascertaining the best way for using instincts" (Brighton, Doctor)

I think it's a completely different kind of experience and I think it depends what your measures or outcomes are, because I think sometime we'll see a person in clinic, they'll have a really good experience with us, it will be a really human experience and actually they might then come back a month later and tell us about something completely different that they hadn't mentioned at the first visit because they feel safe, they've had a good experience. Whereas that is quite a, sort of, impersonal…" (London, HA)

HAs' experience of the pilot led them to feel that the tool had sometimes over-referred patients who were subsequently assessed to have not needed referral, and also to have under-referred patients who they subsequently identified as high-risk. Conversely, the Brighton HA group also stated that many of the patients referred via the triage tool were patients from the waiting room who had already been booked-in to see the HAs. This was seen to both assert the effectiveness of the triage tool in identifying appropriate patients, but also to undermine the purpose and value of the tool:

"*And I think we're picking up the ones anyway that would engage, so they're the ones that, kind of, tend to be known to us and they engage and they're getting through to us in other ways. And the people that won't engage are the people that won't engage, no matter what triage system you're using"* (Brighton, HA).

There was a further challenge to this method in the routine practice in Brighton, where all <18 year olds are routinely screened and receive a thorough assessment. This raised questions regarding the context of the pilot, as the role of an additional triage assessment was not clear:

"*And with the young people they have an assessment anyway, really thorough from a safeguarding perspective, so all under 18s and that bring up anything and everything to do with risk. So that's going to happen anyway, when they're in the room. So, I don't think you need something on top of that, with regards to young people, do you?"* (Brighton, HA)

Several advantages, or opportunities, offered by the triage tool were also discussed, including the potential for the triage tool to enable patients to highlight a risk profile or other issues that they might not feel able to raise face-to-face. This private disclosure was seen as avoiding a potentially embarrassing discussion with a member of staff:

"*So, what I'm saying is they may say something different to the consultant, nurse, whoever they see, and they may be saying what they really feel [overtalking]. If you see what I mean? Because sometimes it's easier to do this than it is to talk to someone face to face. So, it's tricky, yes, you're going to get that I think"* (London, HA).

The Brighton HA group also reflected that the piloted triage tool was potentially more effective than the current process of asking patients to tick key risk assessment questions on a form at reception.

Another potential advantage of a systematised triaging which the London group proposed was the process and structure that it could provide to new members of staff that might lack confidence and skills. The systematised triage was thought to both prompt staff to identify and refer patients that come in for non-STI issues but who have risk profiles that would otherwise go un-assessed.

"I suppose a good thing is that it might make a clinician think more about a patient, particularly if they're repeat attenders for something, and they think that they're really settled and stable and don't need any intervention, this might actually pick it up. So, it might make people explore things more as opposed to thinking; 'Oh, this person's a repeat attender for something'; it might make them look into it more." (London, HA)

"I rarely see the contraception service patients even though we're supposed to be integrated service. So, I would say it really helped clinicians to identify that. But the whole assessment was still down to them: do they feel this person would need to be referred?" (London, HA)

<u>Santé website:</u>

We had limited feedback on the Santé webpage as consenting participants were either not aware of it or had not used it. At least two of the Brighton HAs were not aware that a Santé website existed,

and none of the others made reference to having used the Santé website. There was some brief discussion about the potential value of referral to websites.

"…there are some aspects or some topics maybe that people feel okay to do online, but I think in the area that we're in, in sexual health it's such a sensitive issue… it's quite a vulnerable position to be in to start talking about... So, when it comes to online, I'm not sure how that will translate, but for some people that might be just what they want, because for them, maybe talking doesn't help them or they don't feel it benefits them, and it might be a starting point for some people online" (London, HA).

<u>One-to-one session</u>

This feedback focusses on the health advisor experience, as the non-HA staff had little experience of the intervention. HAs from Brighton and the London HA interview each made conflicting comments about their use of the one-to-one sessions – stating that *'It's what we do anyway'*, but also commenting that the manual provided useful structure and format for these interventions. HAs in Brighton also discussed their existing use of MI as part of their routine work, although they acknowledged the limited amount of MI training that the HA staff had received. Much of the training had taken place many years ago, and they subsequently asked the study team for additional training in MI.

Two of the Brighton HAs stated that they were concerned about the limitations of the intervention manual and felt that it repeated what was already part of their routine practice. They had therefore ignored it (*"I must admit I didn't really use it").* While another Brighton HA participant referred to the value of the manualised MI approach for the structure it provided:

"*I like the part when it gets to the work, I like the MI, I like just being able to, kind of, code or prove what you're doing or, I'm not saying that very well, but measuring what we do somehow"* (Brighton, HA).

The London HA interview in particular valued the manual for its structure and the focus on goal setting, which they felt guided their approach and focussed attention on action planning. They also suggested the focus on action plans provided structure for patients too.

"…just having to do it 100%, thinking about it 100% and doing it 100% was more how it, kind of, focussed the consultations, so that it helped to elicit three goals that the person wants, so, it really made the consultation more structured actually... I think in the normal run of the clinic that wouldn't

be the same way which we would deal with it. So, it, made it more structured for me personally" (London, HA).

Although the London HA welcomed the use of the credit-card-sized Action Plans, none of the Brighton HAs had used the cards, or appeared to be aware of them. As with attitudes towards the Manual, the Brighton HAs described a tension between routine practice already being similar to the intervention process, and the Action Plans not being acted on. *"It's what we would do anyway. The couple of times that I have done it I've forgotten to do an actual action plan, because I wouldn't necessarily do that"* (Brighton, HA). Here again, the London HA interview identified advantages in the structure that the intervention and action plans provided, and related these to both the HAs and the patients:

"*I thought it was a very comprehensive tool, I really did, and a very comprehensive tool, it just, highlighted the bits that you needed to do; and, as I say, the action plan I think was really for me the best part of it" (London, HA).*

<u>Implementation barriers:</u>

A number of implementation barriers were raised during discussions, including the ticketed triage process, and limited staff training. The use of tickets was seen to be a key 'leakage' point at which both patients and staff lost potential referrals. The tickets, which were a work-around in place of the integrated EPR system initially planned, were seen as confusing to patients, and they were lost, abandoned or ignored by patients, and were lost or forgotten by staff. The use of these tickets was introduced as a work-around due to the delays and technical barriers of adapting EPR systems, and this was seen to have introduced several significant barriers to the pilot trial implementation. Integration into the EPR system was identified as a valuable solution that would have avoided many of these 'leakage' points.

"I found them screwed up on the lab floor, stuffed in between peoples' notes, sometimes in the wrong place. Or people just randomly putting notes on my desk, you know, 'Do I give this to you, what do I do with it?' (Brighton, HA)

I think, yes, people who would've been referred to me… basically, because there were few issues with just getting everybody understanding what to do with that bit of paper. (London, HA)

The engagement of doctors, nursing staff and HAs in briefings and training about the conduct of the trial appears to have been inconsistent, fractured and of limited impact. Although all participants

said they found ways to make things work, patients were lost to the study due to confusion about the triage tickets, and the intervention manual was not always read or properly applied by HAs. Among the HAs there was considerable variation in the engagement with the trial, and questionable skills/capacity of HAs to administer an MI intervention. The capacity of many HAs to deliver MI was questioned by some HAs themselves and by participants in the London group.

"I think MI is often talked about as something that everyone does, and I think everyone can do it but equally it can be a very filtered, watered down version of what could be most useful. So I think it's good to make sure if you are offering it, that it's being done by somebody that's really experienced in doing it" (London, Psychologist)

Although most staff in the two pilot clinics had been informed about the pilot's aims and objectives, and all HAs had been through some training on the intervention manual, concerns were raised about the effectiveness of the briefings and training. In the Brighton discussions, a senior nurse had joined the clinic after the pilot had begun and highlighted the necessity of effective, on-going introductions for new staff. This was also recognised to be an issue for junior doctors who may arrive after initial briefings.

"I think if the staff that are seeing them [patients] have a grip of the basic principles of the study, that's more persuasive than them just going, 'Oh, I'm not really sure it's something to do with offering you an intervention if you're a high risk'. There's consistency, isn't there? Everyone saying the same thing, in the same sort of way." (Brighton, Doctor)

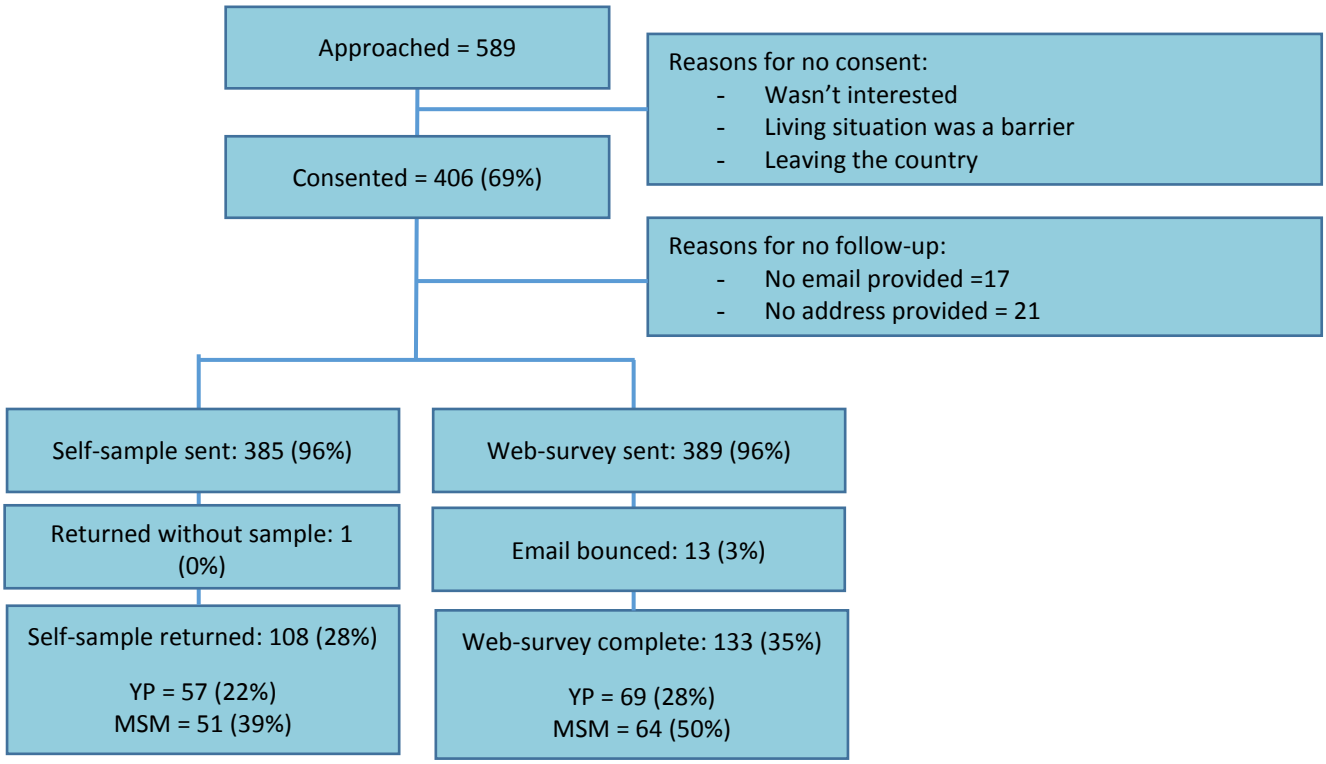
The triage and intervention were generally accepted as viable in these busy clinic environments, and the trial appeared to have had only a very limited impact on the day-to-day clinic work. Even HAs appear to have found the trial and intervention to have been acceptable within their workload – although this may be related to their opinion that most referrals were of patients they would already have expected to see, and the limited numbers of triaged patients who actually made it through to HA appointments. The Brighton HA group suggested that the 'Brighton Express' clinic for <18s, which provides routine and thorough face-to-face assessment of the needs of younger patients, would have been negatively impacted by the trial however.

6.4.5 Follow-up study

In both intervention and control clinics, service users were recruited for a follow-up survey and screening at 6-weeks. The follow-up involved a short web-questionnaire and either a postal self-sample kit or returning to the clinic for a routine STI screening. The initial target was 700 patients

from 8 clinics; as only 6 clinics took part, the target recruitment was revised down to 525 patients. We had originally projected that 180/400 patients from intervention, and 144/300 patients from control clinics would complete follow-up (Figure 13). A total of 406 patients consented to follow-up; recruitment was not achieved at three clinics due to a lack of eligible patients and low consenting rates (**Figure 17**).

Figure 17: Recruitment and follow-up summary



Of the 406 who consented, 273 (67%) were young and 133 (33%) were MSM (33%). Overall 228 (56%) participants did not participate in the web-survey or return a self-sample kit and 64 (16%) completed both follow-up activities. MSM were more likely than young people to participate in the web-survey, to return a self-sample or complete both part of the follow-up (29% versus 10%).

The patients recruited for follow-up represented 2% of all eligible attendees attending the clinics during the study period (**Table 25**). Young people we recruited were generally representative in terms of age, gender and sexual orientation, however our sample had a larger number of young people of black ethnicity. The MSM population we recruited was generally younger than the overall

MSM patient population, and had a higher proportion of bisexual men. We under recruited from MMC compared to the other clinics.

Table 25: Summary of participants recruited for follow-up and the general clinic populations

		Young people		MSM	
		Total (N, %) n = 6,216*	**Recruits (N, %) n = 273**	**Total (N, %) n = 5,738***	**Recruits (N, %) n = 133**
Gender	Male	1,444 (23%)	67 (25%)		
	Female	4,772 (77%)	206 (75%)		
Age	16-20 years	1,890 (30%)	86 (32%)	149 (3%)	9 (7%)
	21-25 years	4,326 (70%)	69 (68%)	610 (11%)	25 (19%)
	26-35 years			1,639 (29%)	43 (32%)
	36-45 years			1,504 (26%)	29 (22%)
	>45 years			1,836 (32%)	27 (20%)
Ethnicity	White	4,296 (69%)	179 (66%)	4,485 (78%)	102 (77%)
	Mixed	455 (7%)	25 (9%)	228 (4%)	11 (8%)
	Asian	331 (5%)	11 (4%)	350 (6%)	7 (5%)
	Black	568 (9%)	52 (19%)	192 (3%)	6 (5%)
	Other	566 (9%)	6 (2%)	483 (8%)	7 (5%)
Sexual orientation	Heterosexual	5,759 (93%)	245 (90%)		
	Homosexual	25 (0%)	2 (1%)	5,286 (92%)	113 (85%)
	Bisexual	404 (7%)	25 (9%)	452 (8%)	20 (15%)
Clinic	Archway	1,667 (27%)	64 (24%)	386 (7%)	11 (8%)
	Brighton	2,134 (34%)	50 (18%)	1,952 (34%)	49 (37%)
	Chelsea	968 (16%)	38 (14%)	1,532 (27%)	36 (27%)
	Croydon*		64 (24%)		12 (9%)
	Darlington	292 (5%)	31 (11%)	37 (1%)	3 (2%)
	MMC	1,155 (19%)	25 (9%)	1,831 (32%)	22 (17%)

* Note: Croydon data was not available at the time of writing the report, the table will be updated once this data is received.

Web-survey:

A total of 990 emails were sent, to 389 service users. 13 (3%) emails bounced as the email address provided by the service user was incorrect (Figure 17). Of the 376 service users who received the link, 133 (35%) completed the survey, and an additional 17 (5%) participants started but did not complete the survey. On average, participants responded to the third email reminder and took a median of 2 minutes to complete the survey.

Young people were significantly less likely to complete the web-survey than MSM (OR: 0.39, 95% CI: 0.25, 0.61), and the completion rate ranged between clinics from 47% in Darlington to 19% at Croydon. **Table 26** presents factors associated with survey completion in MSM and young people.

Table 26: Multivariate analysis of demographic predictors of web-survey completion in MSM and young people

		Young people (N = 273)		**MSM (N = 133)**	
		Completed (n, %)	**aOR* (95% CI)**	**Completed (n, %)**	**aOR** (95% CI)**
Gender	Male	7 (12%)	1.00		
	Female	62 (33%)	***4.35 (1.59, 11.88)***		
Age	16-20 years	27 (36%)	1.00	3 (38%)	1.00
	21-25 years	42 (24%)	0.57 (0.29, 1.11)	12 (50%)	2.54 (0.33, 19.62)
	26-35 years			9 (21%)	0.56 (0.08, 4.01)
	36-45 years			19 (68%)	6.34 (0.77, 52.27)
	>45 years			21 (78%)	5.40 (0.67, 43.26)
Ethnicity	White	47 (30%)	1.00	58 (59%)	1.00
	Mixed	3 (14%)	0.34 (0.08, 1.44)	0 (0%)	
	Asian	1 (10%)	0.27 (0.03, 2.41)	1 (14%)	0.13 (0.01, 1.39)
	Black	14 (27%)	2.13 (0.82, 5.52)	2 (33%)	0.37 (0.04, 3.68)
	Other	4 (67%)	***9.42 (1.34, 66.41)***	3 (43%)	0.70 (0.12, 4.01)
Sexual orientation	Heterosexual	57 (26%)	1.00		
	Homosexual	1 (50%)	3.09 (0.18, 52.65)	53 (48%)	1.00
	Bisexual	11 (50%)	***2.92 (1.08, 7.93)***	11 (58%)	3.10 (0.74, 12.98)
Clinic	Archway	22 (37%)	1.00	5 (45%)	1.00
	Brighton	16 (32%)	0.73 (0.29, 1.82)	25 (53%)	0.82 (0.14, 4.92)
	Chelsea	11 (30%)	1.13 (0.43, 2.96)	15 (42%)	0.45 (0.08, 2.66)
	Croydon	7 (12%)	***0.22 (0.07, 0.66)***	7 (58%)	2.93 (0.30, 28.72)

	Darlington	7 (47%)	0.24 (0.68, 8.71)	1 (50%)	1.13 (0.04, 34.11)
	MMC	6 (25%)	1.33 (0.41, 4.40)	11 (52%)	0.76 (0.11, 5.16)
*Adjusted for: gender, age, ethnicity, sexual orientation, clinic; **Adjusted for: age, ethnicity, sexual orientation, clinic.					

Amongst young people, women were more likely to respond to the web-survey (aOR: 4.35, 95%CI: 1.59, 11.88). Participants recruited from Croydon were significantly less likely to respond, even when the age, gender and ethnicity of the participant was taken into account (aOR: 0.22, 95% CI: 0.07, 0.66). In MSM, no demographic factors were identified that predicted whether participants were more of less likely to respond to the web-survey, although there were trends towards older and white MSM responding. Interestingly, the MSM from Croydon had the highest response rate.

<u>STI screen:</u>

We offered two options for the 6-week follow-up: returning to clinic for a 'quick check' or being posted a self-sample kit. Typically, 'quick check' STI screening appointments involved completion of a very short questionnaire, self-collection of samples, and minimal interaction with clinic staff. In some of the clinics we were unable to offer a 'quick-check' appointment due to limitations with the booking system. Of the 406 participants recruited, 385 opted for the postal self-sample kits and provided address details. The return rate was higher in those who were sent kits (27%) than those who opted to return to clinic (3/21, 14%). Amongst the 108 participants who were successfully screened, there were two chlamydia positive tests and no gonorrhoea diagnosed. We aimed to send the self-sample kits at 6-weeks following recruitment into the study; on average samples were returned at a median of 9 weeks (IQR: 8 – 11).

Young people were significantly less likely to return the self-sample kit than MSM (OR: 0.45, 95% CI: 0.29, 0.72), and the completion rate ranged between clinics from 47% in Darlington to 19% in Croydon. **Table 27** presents factors associated with survey completion in MSM and young people.

Amongst young people, the only factor significantly associated with completing an STI screen was being female (aOR: 3.32; 95% CI: 1.32, 8.38); being older was borderline associated. In MSM, while nothing was statistically significant, there was again a trend towards older men completing the screen compared to younger MSM (63% in >45 year olds versus 0% in 16-20 year olds).

Table 27: Multivariate analysis of demographic predictors of STI screen completion in MSM and young people

		Young people (N = 273)		MSM (N = 133)	
		Completed (n, %)	**aOR* (95% CI)**	**Completed (n, %)**	**aOR** (95% CI)**
Gender	Male	7 (12%)	1.00		
	Female	50 (26%)	***3.32 (1.32, 8.38)***		
Age	16-20 years	13 (16%)	1.00	0 (0%)	
	21-25 years	44 (25%)	2.04 (0.97, 4.28)	8 (33%)	1.00
	26-35 years			13 (30%)	0.73 (0.23, 2.37)
	36-45 years			13 (45%)	1.21 (0.35, 4.12)
	>45 years			17 (63%)	2.03 (0.58, 7.16)
Ethnicity	White	39 (23%)	1.00	45 (44%)	1.00
	Mixed	6 (24%)	1.11 (0.37, 3.30)	3 (27%)	0.68 (0.14, 3.20)
	Asian	1 (10%)	0.27 (0.03, 2.40)	0 (0%)	
	Black	10 (20%)	1.11 (0.43, 2.84)	0 (0%)	
	Other	1 (20%)	1.55 (0.14, 16.81)	3 (43%)	0.95 (0.19, 4.78)
Sexual orientation	Heterosexual	49 (21%)	1.00		
	Homosexual	1 (50%)	4.11 (0.23, 73.35)	45 (40%)	1.00
	Bisexual	7 (30%)	1.83 (0.65, 5.12)	6 (30%)	0.71 (0.21, 2.34)
Clinic	Archway	10 (19%)	1.00	3 (30%)	1.00
	Brighton	11 (23%)	1.21 (0.42, 3.48)	22 (45%)	1.40 (0.29, 6.83)
	Chelsea	12 (32%)	2.48 (0.88, 6.99)	13 (36%)	1.06 (0.21, 5.40)
	Croydon	11 (17%)	1.06 (0.38, 3.00)	5 (42%)	3.90 (0.41, 37.47)
	Darlington	5 (17%)	1.23 (0.34, 4,44)	0 (0%)	
	MMC	8 (32%)	3.10 (0.94, 10.25)	8 (36%)	1.18 (0.21, 6.70)

*Adjusted for: gender, age, ethnicity, sexual orientation, clinic; **Adjusted for: age, ethnicity, sexual orientation, clinic.

6.5 Discussion

We conducted a pilot feasibility study to determine the acceptability of our intervention package, the feasibility of implementing the package and the feasibility of conducting a subsequent cluster

RCT. We encountered multiple challenges in both trial and intervention feasibility, but found some evidence to support acceptability; however we also faced challenges in collecting all the data we planned to assess acceptability and feasibility. **Table 28** summarises the pilot trial objectives and specific outcomes that we intended to collect, and those which we actually managed to collect.

Table 28: Summary of pilot trial outcomes planned and measured

Planned objective and measure	Measurement status	Comments
Acceptability of the intervention to users and HCP		
1. Proportion of eligible service users who attend the clinic that were assigned a score by the triage tool	Collected as planned (Table 23)	This data was collected through the tablet triage, and compared to the total attendances recorded in the clinic EPR system.
2. Proportion of those who were classified as high risk who are offered the intervention	Partially collected (Table 23)	This data was collected through the table triage system and then linked to the clinic EPR system in Brighton, and to paper forms in Archway. This linkage relied on HCPs asking for the triage ticket and then filling information during the consultation, and this was incomplete for a proportion of service users, limiting our conclusions.
3. Proportion of those who were offered the intervention who took up the intervention		
4. Proportion who took up the intervention who completed the intervention		
5. Reasons for not completing the intervention from the qualitative study of participants	Collected as planned (Section 6.4.3)	We conducted 16 interviews with service users, identifying barriers to attending the 1:1 and accessing the webpage.
6. Acceptability of the intervention from the qualitative study of the staff	Partially completed (Section 6.4.4)	We conducted FGDs and interviews with HCPs from Archway and Brighton, and identified barriers and opportunities for the intervention in these two settings.
Feasibility of delivering the interventions		
1. The total time spent by service users within the clinical service compared to normal	Data not collected	We did not collect any baseline data from the clinics on attendances, or duration of consultations. Therefore, we did not have anything to compare the pilot period to. We were also unable to collect data on consultation durations from the EPR system.
2. Total number of service users seen and STIs diagnosed, compared to normal	Data not collected	
3. Average consultation time compared to normal	Data not collected	
4. Number of patients seen by health advisors compared to normal	Partially collected (Table 23)	
5. Extra HCP time required for the intervention	Partially collected (Section 6.4.2)	Health advisors were asked to record how long the 1:1 session lasted in the EPR system. This data was incomplete.
Feasibility of obtaining follow-up outcome data		
1. Proportion of eligible service users who consented to the follow-up		These data were collected by study staff and then compared to all

2. Proportion of eligible service users who were contactable at 6 weeks and complete a questionnaire	Collected as planned (Figure 17 and Table 25)	attendances as recorded by the clinic EPR. We were unable to make this comparison for one clinic, who did not provide their EPR data.
3. Proportion who complete follow-up tests		

6.5.1 Intervention acceptability

The intervention package consisted of three components, the triage, the webpage and the one-to-one consultation. The first step, triage, was conducted on tablet computers with study staff asking patients on arrival to complete it before their appointment. This was a resource intensive approach to triage and we only captured 16% patients who attended during the pilot period, and could not capture reliably the number of patients who refused to take part. However, those patients who we did engage with the triage process completed the process 97% of the time – this suggests that the process was acceptable and that the tablet-based self-triage was usable. This was supported by the interviews with patients, who generally found this process to be acceptable, and the types of questions asked unsurprising. This is similar to the findings from other self-triage evaluations in sexual health which have found the process, whether using pen and paper, electronic devices or online, were all acceptable.[89, 137] There is also evidence to suggest that self-triage could elicit more reliable information about sexual risk, compared to face-to-face assessments.[138] However, the difference in completeness of data between the pilot and the triage development dataset may have resulted in the tool not performing as anticipated. Further work to externally validate, or refine the model using different clinic populations would be required before the value of standardised implementation could be determined.

The acceptability was less consistent among healthcare staff. Healthcare providers expressed particular concern over the ability of the triage tool to accurately identify who they perceive to be 'high risk'. At the same time, there were questions about the value of having a tool if it was identifying patients who would already be flagged as 'high risk'.

While in principle the concept of a webpage was acceptable to patients and providers, engagement with the intervention webpage was extremely limited, demonstrating a disconnect between acceptability and uptake. This may have been because of the short period for the pilot, so that it had not been well embedded into the operation of the clinic. However it is a common theme in internet-based digital interventions, with effectiveness closely linked to engagement and reach,[28] and more methods for sharing the webpage with patients could have been employed.[139]

The one-to-one session was commented upon by both patients and providers suggesting that this was an acceptable approach, although this was not based on first-hand experience for most of the participants. Of those who should have been referred for the one-to-one intervention, only 18% were recorded as having completed it, which raises questions about actual acceptability. Health advisors, who delivered the one-to-one sessions, were not all positive about it. Some considered it something they already did and therefore the need for the manualised approach was questioned. This would likely cause challenges in terms of fidelity of delivery of the implementation across services and individual providers, if HAs considered the intervention only a reinforcement of their current practice.

6.5.2 Intervention feasibility

We were unable to collect our originally proposed metrics for intervention feasibility (Table 28); however we collected several different types of data about the ability and willingness of clinics to pilot the intervention package. Firstly, we had planned to pilot in four clinics and specifically aimed to engage a level-2 service. While Brook agreed to the pilot, and gave high-level support for the project, we encountered several practical limitations and were ultimately unable to include them. These barriers were mainly related to resources rather than the acceptability of the structure of the intervention. Similarly, the two London GUM clinics agreed to the pilot, but were unable to implement. They raised significant issues with staffing and clinic space. In order to conduct a trial in these settings, resources would need to be provided.

On the other hand, Brighton were able to implement the intervention package, mostly within existing clinic resources, suggesting that not all sexual health services are experiencing the same level of resource constraint. In Brighton, members of clinical staff (including a HA) were part of the project management group, and this continued engagement may have been one of the reasons for engaging with the pilot. In a large cluster RCT it would be essential to engage both management and healthcare staff at potential sites to improve the prospects for a trial.

While incorporating the triage tool in the EPR systems in Brighton and Archway was theoretically possible, we were unable to demonstrate feasibility (or therefore acceptability) of this approach within the timescale and resources of this study. This limited our ability to monitor process data on the number of patients triaged, referred and who attended. It also made the patient pathway less seamless, with healthcare providers needing to be engaged enough with the intervention to ask patients for their triage slip, and then refer them to a HA if indicated. We had envisaged that the EPR systems would run the triage without prompt and then inform the healthcare provider during the

consultation of the result, without the provider needing to remember. We are unable to comment on whether this approach would have improved provider engagement with the intervention process; however the system piloted would not support a larger trial.

6.5.3 Trial feasibility

We worked on the premise that a full trial would be cluster randomised and powered to detect a reduction in STI diagnoses. In order to test the feasibility of this trial design, we recruited a sub-set of patients from intervention and control sites to be followed-up 6-weeks after recruitment. We did not recruit the 700 planned patients, partly due to our inability to engage with all eight clinics we had originally planned. However, we also recruited fewer patients within clinics for a range of reasons. These included patients who were ineligible because they only temporarily in the country, or those who lived with their partner or parents and did not want to share their contact information in case this resulted in accidental disclosure of their clinic attendance.

In addition, of those who we did consent to be followed-up, return rates for both the web-survey and STI screen were lower than we had projected. Approximately one third of participants engaged with the follow-up process, and there were differences in the characteristics of those who engaged. MSM were more likely to engage than young people. Heterosexual women were more likely to engage than heterosexual men, and older MSM were more likely to take part than younger MSM. In a trial, these differences could bias the primary outcome. Additionally, there were differences both in recruitment and follow-up rates between clinics, with Croydon having lower follow-up in young people, but higher in MSM, after adjusting for other factors. This suggests that there may other factors involved which we have not captured. In a cluster randomised design it would be important to understand how clinic features influenced both the trial implementation, as well as ascertainment of the primary outcome. These pilot data suggest this could be problematic.

6.5.4 Strengths and limitations

A key strength of the pilot was the inclusion of clinics from different geographical locations, with different patient characteristics and risk behaviours. This meant that data, while limited, was likely to include different perspectives and experiences from both healthcare providers and patients. We were only able to pilot the intervention package effectively in two clinics; this is also a limitation. As the clinics implemented the intervention differently, we are unable to directly compare their experiences or generalise to sexual health services in England, considering the diversity of standard

practice observed across services. In particular, we were unable to draw conclusions about trial feasibility and intervention acceptability in level-2 services.

The interviews and FGDs with patients and healthcare providers included some participants who had not had any interaction with the intervention package, or in the case of patients they had not realised that they were part of an intervention. Therefore, some of the views expressed were more theoretical, rather than based on experience. We were aiming to understand the barriers to delivering the intervention, and the reasons for the intervention being acceptable, or not. While some participants provided concrete examples from their experience, many were only able to offer opinions based on a description of what was offered.

We recruited a large number of participants to the follow-up study, albeit less than planned (406/700), meaning the descriptive analyses lacked power. We found very few statistically significant factors associated with completing follow-up. Similarly, with only two clinical services implementing the intervention pilot, it is not possible to understand fully the potential differences between clinic types.

6.6 Conclusion

We were able to pilot the intervention package and recruit patients to be followed-up for an STI screen 6-weeks after their visit to a SH clinic. However, we observed considerable barriers both to implementing the intervention and conducting the follow-up. These implementation barriers included the inability to recruit a level-2 service to take part in the pilot, not being able to adapt an EPR system to include the triage process, and a lack of trained staff time to deliver the one-to-one session. The 6-week follow-up suffered from lower than expected recruitment and completion, although differences in the types of patients who completed follow-up were noted. These differences could influence interpretation of the results of a trial powered for STI outcomes. In spite of these challenges, we found that the intervention was generally perceived as acceptable.

Chapter 7: Work Package 6 – Determination of the feasibility of an RCT, and further recommendations

7.1 Introduction

The systematic review (WP1) confirmed that there are several interventions which have shown modest, but significant, effects on sexual behaviour and STI outcomes. Both service users and service providers expressed a preference for one-to-one and digital interventions. Clinics indicated that these types of interventions have been or could be feasibly delivered within their settings. The specification and manualisation of one-to-one intervention, which required more development work than expected, was nonetheless completed, and pre-trial evaluation by service providers and users was positive. However, attempts to execute a pilot trial highlighted major service-level feasibility challenges. Implementing the triage tool, albeit not fully developed due to insufficient data being available to refine the model, was hampered by unresponsive and inflexible IT systems and support. But the biggest challenge was the inability of services to deliver. This can be summarised as being due to a combination of 'bad timing', and a service provision environment undergoing unprecedented upheaval, with an almost universal demand from commissioners that providers accommodate a reduction in funding for services.

WP6 was designed to include the development of an outline protocol for a cluster RCT, based on the elements developed and tested in the Santé project to that point. However, in the light of the findings of the pilot, our conclusion is that the postulated cluster RCT as a whole is not feasible at the current time. Nonetheless there are important outputs from the project which could lead to the implementation and evaluation of an important public health intervention.

7.2 Method

The data from each of the work packages were reviewed and synthesized by the Project Management Group and a consensus arrived at regarding the feasibility of an RCT. Discussions focussed on the data collected related to: intervention package acceptability; intervention feasibility; trial feasibility. Conclusions in respect of each of these were agreed, and presented to the Project Steering Committee and PPI group for input and feedback.

7.3 Results and discussion

7.3.1 One-to-one behavioural intervention

Throughout the project there was support from SH service users for behavioural interventions, and more specifically for healthcare provider-based talking interventions. This is consistent with the Sexual Health Framework published by the DH, which prioritises prevention through behaviour change, alongside access to sexual and reproductive health services.[6] Brief one-to-one sessions are already a recommended activity within SH services, and therefore our intervention package could capitalise on existing best practice, by providing an evidence-based structured intervention. However, despite being supported by providers and desired by patients, there was limited engagement with the one-to-one intervention in the small number of settings where it was trialled and resistance from clinics in implementing the pilot due to a lack of resources. As a result, we did not obtain as much evidence for the feasibility of delivery as we had hoped. Any future trial or implementation should include a further pilot of the acceptability and feasibility of delivery, and consider the costs of delivery and potential cost-benefit.

7.3.2 Digital intervention

The concept of a digital intervention was popular with service users and providers. The systematic review identified a number for which there was at least some evidence of efficacy, however there was none that could be included in the pilot. The interventions were unavailable for a variety of reasons including licencing issues, being offline or in non-current format, or were out of date or culturally or linguistically inappropriate. We used a placeholder to try to measure potential engagement, but other aspects of the pilot trial implementation limited the available data.

A digital intervention places the least demand on clinic resources. We postulated that the digital intervention would be the best option in terms of deliverability for the majority of service users who are at lower risk. There is still a need to demonstrate that it could be delivered and engaged with by a sufficient proportion of those at risk to have a population level impact on STI rates.

7.3.3 Triage tool

The analysis of GUMCADv3 data led to a predictive model that could be implemented as an automated triage tool. The work in WP2 demonstrated that such a tool is feasible and, with further behavioural data, easily refined so as to improve its performance. Implementing the tool for the

pilot was not optimal, requiring alternative methods of data collection which was less robust, and more demanding of resources, at least in the short period available for the trial. Although there was scepticism from some service providers, others could see the value of a systematic evaluation of risk which could also be used to direct users to different STI screening pathways. It could also be easily adapted for use in conjunction with on-line access to STI testing. The wider application of this technology means that it is more likely to be supported and prioritised for implementation.

We found this to be contradictory, as the pilot provided an opportunity to generate an evidence-base on the value of these types of interventions, which could then be used to support their continued implementation and commissioning. We found that the role of HAs differed between clinics, and that much of these differences were the result of local commissioning decisions, rather than based on local patient need or staff skills. In order for our intervention package to be successfully delivered within SH clinics using existing resources, a commitment from commissioners to support these sorts of services would be required. However, we were unable to generate the evidence which commissioners would likely need to make the decision to support these services. This is a considerable issue if research into behavioural interventions in sexual health services assumes a certain level of existing resources.

7.3.4 RCT feasibility

Overall, based on the experience of trying to implement the pilot, and the data collected, we concluded that trialling this intervention package using a cluster RCT approach is not feasible in existing SH services. Of the several factors identified, some could be mitigated if funding for the intervention delivery was met by the trial (including the HA and clinic staff time, adaptation of the digital intervention and implementation of the triage tool in clinic EPR systems). However, as the intervention effect size would still likely to be small, the cost-effectiveness may still rely on delivering the eventual service within existing resources. With the immediate constraints on resources for sexual health services nationally, the case for prioritising this prevention strategy is difficult to make, without the evidence for the very study that cannot be delivered.

Other concerns with conducting a cluster RCT were highlighted.

Firstly, we found considerable variability in services, both in terms of their current resources (which was particularly apparent with clinics going through re-commissioning and how this impacted their resourcing), patient pathways and interventions which they currently offer. This was an issue for multiple reasons:

- Standardising clinic pathways and services to the degree required for a trial would be challenging, meaning that local adaptations to the intervention package would likely be needed. The inability to ensure standardised implementation would undermine the evaluation.
- The intervention may not be sufficiently different from standard care to demonstrate any intervention effect, as many clinics currently offer some form of one-to-one session or refer patients to online resources. As control sites would need to be able to offer their current minimum standard of care, a well-resourced control clinic with MI trained HAs may not be materially different from an intervention clinic.

Secondly, there were concerns around the use a standardised triage tool, developed using national-level data, applied to an individual clinic setting. We found a higher proportion of high-risk patients in the pilot sites than seen in the dataset used to develop the tool. This is not surprising as the proportion of MSM, for example, attending clinics varies substantially. If only a fixed, and small, proportion of patients can be offered the one-to-one intervention, there could be substantial inequality in who is offered the intervention package between services, or unfeasible numbers of patients requiring intervention in some clinics. This could impact on the overall effect of the intervention at each of the clinics, and have significant design implications.

Thirdly, the rate of follow-up completion was much lower than would be needed for a trial, and there were differences in those clinic attendees who agreed to take part and those who completed the STI screen, compared to those that did not. This suggests that the primary outcome measure in a cluster RCT could suffer from material biases.

Finally, we encountered significant research and development (R&D) barriers during the project, which resulted in delays to starting the pilot study, and this may have been one reason for the resulting poor engagement from clinics. Certainly the available time to complete the pilot was reduced and it was not possible to accommodate, for example, postponing implementation of the pilot until after a clinic moved, or a new IT system was implemented. During the period of the project, the process for gaining national and local ethical approvals changed, with the new system aiming to decrease the amount of local approvals required for multi-site projects. However our experience of the process did not reflect this, with each pilot site required different documentation, checks and time to process. These delays also affected sponsor approval. Overall, it took nine months to complete the R&D process for the pilot, which involved liaising with only five NHS trusts. A large cluster RCT would require considerably more clinics to be involved, and at present delivering

that represent a risk to the project. Any delay would also incur research staff costs, and run the risk, as in this pilot, of a clinic no longer being able to deliver the intervention during this period.

7.3.5 Alternatives designs

We had initially planned that any large trial for the intervention package would need to be cluster randomised, because the intervention required a service-wide change in clinic practice and procedure. However, as we determined that there were significant difficulties with this design, several related to the clusters themselves, two alternative designs were considered, which do not rely on cluster-level randomisation.

Individual randomisation: Elements of the intervention package could be well-suited to individual randomisation, such as the triage being randomly applied to different patients. However, there are still concerns about contamination between the intervention and control patients due to the service-wide nature of the intervention. Employing study staff to deliver the intervention could mitigate this risk, but would have cost implications, and this implementation method would need piloting.

Step-wedge roll-out: As the intervention package was in principle acceptable and used evidence-based elements, the intervention package could be routinely implemented within clinics, if commissioners agreed to support it. A stepped-wedge trial, which did not involve randomisation or the need for the level of standardisation that an RCT would require, could allow for some adaptation of the intervention within each clinic. If this was combined with changes to GUMCAD, as currently being implemented for the Impact trial of HIV pre-exposure prophylaxis, then the outcome measures could be collected as part of routine data collection. This would allow for an evaluation of real world implementation. However, this approach would be unable to establish the effect size, and requires funding agreement from commissioners.

We did not conclude that either of these alternative designs would be feasible for a trial within existing resources. Either would require additional developmental work, and piloting.

7.3.6 Further developmental work and recommendations

To realise the potential to implement the intervention package, or elements of it, there are key areas that require further development.

Digital intervention: A digital risk reduction intervention would need to be developed, or adapted from one of the trialled interventions, for which materials are available. Following the development process, additional piloting work would be needed to improve and incentivise engagement, such as the processes used in the pilot (e.g. specific text message promotion).

One-to-one session: One concern with the one-to-one session, which was supported by our pilot work, is that due to being similar to HA's current practice there may be issues with intervention fidelity. Furthermore, different SH providers, have different levels of training. Some MI training is required, but is not universal even among HAs. Extensive training was considered unfeasible within current clinics resources for the pilot. We designed the training to be pragmatic within existing clinic resources, assuming a baseline level of MI experience amongst staff, which was not always found. Additional work would be needed to evaluate how well this training module could be implemented, the gaps it would leave and how well those healthcare providers implemented the intervention session, rather than defaulting to their usual practice.

EPR-based triage tool: While implementing the triage tool within clinic EPRs seems feasible, we were unable to actively demonstrate this within the pilot. A key challenge in this was communicating how the triage should be presented in the front-end of the system (i.e. what the HCP interacts with). Therefore, further work which includes the participation of clinical staff and engages with multiple different EPR providers would be needed. An important aspect of this would be how to standardise to a sufficient level, both the way in which the data is captured and processed, but also the end-user experience. In addition, further work on the external validation or refinement of the triage tool is needed using more complete data, to demonstrate whether it could be usefully rolled-out either in clinics or in online pathways.

Follow-Up: Due to the relatively poor follow-up rates, further investigation and piloting of different methods (e.g. phone call reminders) and potential incentives (e.g. vouchers for samples returned) to improve follow-up rates would be needed. Specifically these would need to assess whether heterogeneity in follow-up increased or decreased by location and type of clinic, and the service user demographics.

Economic evaluation: We had intended to estimate the cost of delivering the intervention package as part of the pilot trial, but were unable to collect the data we needed to do this. At the outset, it was envisaged that the intervention would be delivered within existing resources, by reallocation of staff time in particular, from existing work with patients. As such, an economic analysis might be less useful. However it was clear that to deliver the intervention, existing resources were not sufficient, and an economic evaluation is needed. One of the main barriers we faced in conducting the pilot

trial was delivering the one-to-one, and having a clear understanding of what resources a clinic would require to deliver the intervention package could have improved our ability to make conclusions on feasibility.

Dissemination: Further communication between service providers, commissioners and service users is needed if the proposed intervention approach was to be trialled or undergo further piloting. A barrier we faced was the disconnect between service provider and user's preference for risk reduction and what commissioners are prioritising for funding. We plan to disseminate the findings from this project to both service providers and commissioners, through this report, academic publications and conference presentations, to encourage this communication.

Chapter 8: Conclusion

8.1 Summary of Main Findings

Our key findings from this feasibility study were:

- Evidence-based brief behavioural interventions that could be appropriate to SH clinics in the UK are available. But there are considerable barriers to the implementation of sustainable digital interventions and additional infrastructure would be needed if this approach were to be pursued. A more intensive, but still brief, one-to-one intervention based on the results of published trials was specified and could be deliverable.
- Both HCP delivered talking interventions and online interventions were more desirable than other intervention formats, and were considered acceptable to providers and patients during piloting. However, the assessment of acceptability was limited in the project because of limited implementation.
- Risk of an STI diagnosis could be predicted with reasonable accuracy using a limited number of routinely collected demographic and behavioural data; however this approach to triage was met with contradictory opposition by some HCPs and EPR software providers. The acceptability of conducting self-triage by patients though could provide opportunities in the context of online patient pathways.
- During the course of the project, re-commissioning and reductions to sexual health clinic resources and staffing resulted in considerable challenges to involving clinics in the pilot. This was especially pronounced in level-2 services, which despite high-level support and interest in the project were unable to take part. Plans for future work in this area will need to consider the full resource implications of implementing and evaluating brief behavioural interventions.
- Participant recruitment for a 6-week follow-up demonstrated biases in those who agreed to participate and those who completed the follow-up, raising concerns about the ability to conduct a large-scale trial with STI outcomes. Different approaches to incentivising participants should be considered going forward.

8.2 Overall Conclusion

We concluded that a cluster RCT of the Santé intervention package would be very difficult to undertake in sexual health services in England at the present time. However, we are limited in our ability to draw a more definitive conclusion on feasibility, primarily due to the smaller than expected number of services which took part in the pilot study. In the literature review we found RCTs of behavioural interventions which had been successfully undertaken. However, a large scale pragmatic cluster RCT could only be delivered if the resources were available for the interventions. At the time of this study, resource limitations and major service reconfigurations meant that there were neither the resources nor the necessary service engagement to deliver such a trial.

With limited resources and service re-organisation, there is a shift in focus of commissioning away from face-to-face consultation, to self-testing and online patient pathways. While there is agreement that there is a need for behavioural interventions, including one-to-one sessions for the highest risk groups, the heterogeneity of services means that the design and implementation of a large-scale national trial would be challenging. Digital interventions could be implemented in conjunction with new care pathways for STI testing but these have not been widely commissioned. Further developmental work is required to see how behavioural interventions can be incorporated into the new models of service delivery. Alternative evaluation designs are likely to be required to provide evidence of efficacy and cost-effectiveness at that point.

This project has wider lessons for sexual health services. We found both staff and patients valued the human interaction of one-to-one consultations, with patients particularly concerned that services should be tailored to their specific and varied needs. Reducing the flexibility of the response in sexual health services, and replacing it with standardised online pathways may risk disengaging patients and reduce the opportunity to exploit teachable moments in the clinical setting. On the other hand, lower cost alternative models of service delivery for the majority of low-risk patients may lead to resources being released for the delivery of more intensive behavioural interventions for those most at risk. On-line and remote testing models will provide an opportunity to exploit digital interventions although as we found, these will require further development.

The re-commissioning and service reorganisation that coincided with the period of this study was a considerable barrier to effective piloting of the intervention package. Further development of the proposed intervention package, and a commitment to funding of the intervention during its evaluation would be required if the potential for this approach to reducing STI rates is to be realised.

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Author contributions

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Carrie Llewellyn (Reader, Applied Behavioural Medicine) was the co-CI, leading work package four and substantially contributing to the overall design and delivery of the remaining work packages.

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Publications

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Data sharing

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

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Appendix 1: Medline search strategy (WP1)

1. exp Health Promotion/
2. exp Health Education/
3. exp Sex Education/
4. exp Preventive Health Services/
5. exp Preventive Medicine/
6. exp Primary Prevention/
7. Public Health/
8. exp Social Medicine/
9. exp Behavior Therapy/
10. exp Health Behavior/
11. exp Sexual Behavior/
12. exp risk reduction behavior/ or exp risk-taking/ or exp condoms/
13. exp unsafe sex/
14. exp safe sex/
15. exp sexual abstinence/
16. exp Sex Education/ or exp sexology/
17. ((prevent$ or reduc$ or educat$ or promot$ or increas$ or decreas$ or facilitat$ or barrier$ or encourag$) adj2 (sex$ or HIV or STI or STIs or STD$)).ab,ti.
18. Attitude to health/ or health knowledge, attitudes, practice/

OR

20. exp Sexually Transmitted Diseases/
21. exp chancroid/ or exp chlamydia infections/ or exp lymphogranuloma venereum/ or exp gonorrhea/ or exp granuloma inguinale/ or exp syphilis/
22. exp HIV infections/ HIV*.ti,ab. /acquired immuno deficiency syndrome/ Acquired Immunodeficiency Syndrome/
23. Herpes Genitalis/
24. Condylomata Acuminata/
25. (HPV or human papilloma$).ab,ti.
26. ((genital or venereal) adj2 wart$).ab,ti.
27. (STI or STIs or STD or STDs).ab,ti.
28. (Sexual$ transmit$ adj3 (infect$ or disease$)).ab,ti.

OR

29. exp Adolescent/

30. (young$ adj2 (men or man or woman or women or female$ or male$ or people or person)).ab,ti.

31. (teenage$ or adolescen$ or youth or youths).ab,ti.

32. exp men/

33. ((gay adj2 man) or men).ti,ab.

34. (men$ adj6 men).ab,ti.

OR

35. 19 and 32 and 39-41. randomized controlled trial.pt.

36. controlled clinical trial.pt.

37. random$.ti,ab.

38. control$.ab,ti.

39. (effectiveness or trial).ti.

40. placebo.ab,ti.

41. one to one intervention$.ti,ab.

42. intervention$.tw.

43. ((control$ or experimental or compar$) adj2 (Group$ or trial$ or study or studies or evaluat$ or condition))